

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

TRANSCRIPT OF PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF: UNITED STATES ATTORNEY'S OFFICE
BY: JOHN C. BOSTIC
JEFFREY B. SCHENK
150 ALMADEN BOULEVARD, SUITE 900
SAN JOSE, CALIFORNIA 95113

BY: ROBERT S. LEACH
VANESSA BAEHR-JONES
1301 CLAY STREET, SUITE 340S
OAKLAND, CALIFORNIA 94612

(APPEARANCES CONTINUED ON THE NEXT PAGE.)

OFFICIAL COURT REPORTER:

IRENE L. RODRIGUEZ, CSR, RMR, CRR
CERTIFICATE NUMBER 8074

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

APP E A R A N C E S: (CONT 'D)

FOR DEFENDANT HOLMES: WILLIAMS & CONNOLLY LLP
BY: KEVIN M. DOWNEY
LANCE A. WADE
KATHERINE A. TREFZ
725 TWELFTH STREET, N.W.
WASHINGTON, D.C. 20005

LAW OFFICE OF JOHN D. CLINE
BY: JOHN D. CLINE
ONE EMBARCADERO CENTER, SUITE 500
SAN FRANCISCO, CALIFORNIA 94111

FOR DEFENDANT BALWANI: ORRICK, HERRINGTON & SUTCLIFFE LLP
BY: WALTER F. BROWN, JR.
RANDALL LUSKEY
THE ORRICK BUILDING
405 HOWARD STREET
SAN FRANCISCO, CALIFORNIA 94105

BY: STEPHEN A. CAZARES
SUITE 3200
777 SOUTH FIGUEROA STREET
LOS ANGELES, CALIFORNIA 90017

FOR THE FDA: UNITED STATES SECURITIES AND EXCHANGE
COMMISSION
BY: MARCI NORTON
JACKIE MARTINEZ-RESLY
DOUG WEINFELD

TELEPHONICALLY: BY: STACY AMIN
PERHAM GORGIA

1 SAN JOSE, CALIFORNIA JANUARY 13, 2020

10:05AM 2 P R O C E E D I N G S

10:05AM 3 (COURT CONVENED AT 10:05 A.M.)

10:05AM 4 THE COURT: LET'S CALL 18-258, UNITED STATES VERSUS

10:06AM 5 HOLMES, BALWANI.

10:06AM 6 IF I COULD CAPTURE THE APPEARANCES OF THE PARTIES, PLEASE.

10:06AM 7 MR. LEACH: THANK YOU, YOUR HONOR. GOOD MORNING.

10:06AM 8 ROBERT LEACH FOR THE UNITED STATES. TO MY LEFT IS

10:06AM 9 JEFF SCHENK, JOHN BOSTIC, AND I WANTED TO ESPECIALLY INTRODUCE

10:06AM 10 VANESSA BAEHR-JONES WITH MY OFFICE. SHE FILED A NOTICE OF

10:06AM 11 APPEARANCE A MONTH OR TWO AGO, BUT THIS IS HER FIRST LIVE

10:06AM 12 APPEARANCE BEFORE YOU.

10:06AM 13 THE COURT: THANK YOU. GOOD MORNING.

10:06AM 14 MS. BAEHR-JONES: GOOD MORNING, YOUR HONOR.

10:06AM 15 MR. WADE: GOOD MORNING, YOUR HONOR. LANCE WADE

10:06AM 16 FROM WILLIAMS & CONNOLLY FOR MS. HOLMES. WITH ME FROM MY FIRM

10:06AM 17 ARE MY COLLEAGUES, KEVIN DOWNEY AND KATHERINE TREFZ.

10:06AM 18 THE COURT: THANK YOU.

10:06AM 19 MR. WADE: AS WELL AS COCOUNSEL, JOHN CLINE. AND

10:06AM 20 MS. HOLMES IS PRESENT.

10:06AM 21 THE COURT: THANK YOU. GOOD MORNING.

10:06AM 22 MR. CAZARES: GOOD MORNING, YOUR HONOR.

10:06AM 23 STEPHEN CAZARES AND WALT BROWN FOR MR. BALWANI WHO IS NOT

10:06AM 24 PRESENT.

10:06AM 25 THE COURT: AND REMIND ME AGAIN ABOUT HIS ABSENCE.

10:06AM 1 MR. WADE: MR. BALWANI IS, ALONG WITH MY COCOUNSEL,
10:06AM 2 MR. COOPERSMITH, ARE ATTENDING DEPOSITIONS IN THE PARALLEL
10:06AM 3 S.E.C. CASE IN WASHINGTON, D.C.
10:06AM 4 THE COURT: I SEE. OKAY. ALL RIGHT. I THINK THE
10:07AM 5 GOVERNMENT HAD NOTICE OF THIS. WEREN'T YOU AWARE OF THIS?
10:07AM 6 MR. SCHENK: WE FOUND OUT FRIDAY AFTERNOON, YOUR
10:07AM 7 HONOR, YES.
10:07AM 8 THE COURT: THANK YOU. THIS MATTER IS ON THIS
10:07AM 9 MORNING FOR A STATUS CONFERENCE, AND THERE HAS BEEN SOME
10:07AM 10 FILINGS BY THE GOVERNMENT REGARDING THE DISCOVERY.
10:07AM 11 AND I DID CAPTURE YOU AND I HAVE READ AND REVIEWED YOUR
10:07AM 12 JOINT STATEMENT. THANK YOU FOR THAT.
10:07AM 13 IS THERE ANYTHING THAT ANYONE WISHES TO ADD TO YOUR JOINT
10:07AM 14 STATEMENT, UPDATE ME ON ANYTHING THAT HAS CHANGED?
10:07AM 15 APPARENTLY NOT.
10:07AM 16 MR. LEACH: NOTHING THAT HAS CHANGED, YOUR HONOR.
10:07AM 17 THERE WERE SOME ARGUMENTS THAT I WOULD LIKE TO MAKE WITH
10:07AM 18 RESPECT TO THE MOTION, BUT I DON'T THINK WE HAVE ANY UPDATE ON
10:07AM 19 WHAT WAS INCLUDED IN THE JOINT STATUS.
10:07AM 20 THE COURT: OKAY. ALL RIGHT. SO AS I UNDERSTAND
10:07AM 21 IT -- EXCUSE ME. DO WE HAVE ANY APPEARANCES TELEPHONICALLY?
10:07AM 22 LET'S CAPTURE THOSE.
10:07AM 23 IS ANYONE PARTICIPATING TELEPHONICALLY? IF YOU COULD,
10:08AM 24 COULD YOU PLEASE STATE YOUR APPEARANCE.
10:08AM 25 MS. AMIN: YOUR HONOR, MY NAME IS STACY AMIN. I'M

10:08AM 1 THE CHIEF COUNSEL AT THE FOOD AND DRUG ADMINISTRATION.

10:08AM 2 THE COURT: THANK YOU. GOOD MORNING. THANK YOU FOR

10:08AM 3 JOINING US.

10:08AM 4 MR. GORGI: HELLO. THIS IS PERHAM GORGI. I'M

10:08AM 5 DEPUTY CHIEF COUNSEL FOR LITIGATION AT THE FDA OFFICE OF CHIEF

10:08AM 6 COUNSEL.

10:08AM 7 THE COURT: THANK YOU. THANK YOU FOR JOINING US.

10:08AM 8 IS THERE ANYONE ELSE PRESENT TODAY FROM THE FDA?

10:08AM 9 MR. LEACH: YES, YOUR HONOR. I INTENDED TO

10:08AM 10 INTRODUCE THEM DURING MY REMARKS, BUT WE ALSO HAVE THREE

10:08AM 11 ATTORNEYS FROM THE FDA IN WASHINGTON, D.C. HERE WITH US:

10:08AM 12 MARCI NORTON, SENIOR COUNSEL; JACKIE MARTINEZ-RESLY, ALSO WITH

10:08AM 13 THE OFFICE OF CHIEF COUNSEL; AND DOUG WEINFIELD, WHO IS AN

10:08AM 14 E-DISCOVERY LAWYER WITHIN THE FDA OFFICE OF CHIEF COUNSEL.

10:08AM 15 THEY'VE COME OUT HERE FROM WASHINGTON FOR THIS HEARING.

10:08AM 16 THE COURT: WELL, GREAT. THANK YOU. GREAT.

10:08AM 17 WELCOME TO CALIFORNIA. I KNOW YOU'LL ENJOY THE WEATHER HERE.

10:08AM 18 I THINK WE SPOKE TELEPHONICALLY AT OUR LAST HEARING,

10:08AM 19 MS. MARTINEZ-RESLY AND MS. NORTON, IF I AM NOT MISTAKEN?

10:09AM 20 MS. NORTON: CORRECT.

10:09AM 21 MS. MARTINEZ-RESLY: CORRECT.

10:09AM 22 THE COURT: THANK YOU. LET'S SEE, BEFORE WE MOVE

10:09AM 23 INTO THE MOTION, AND THIS IS THE GOVERNMENT'S MOTION TO EXTEND

10:09AM 24 TIME I BELIEVE IT IS.

10:09AM 25 AND THIS IS -- WELL, I HAD THE DOCKET LIST HERE.

10:09AM 1 MR. LEACH: YOUR HONOR, THE MOTION IS ECF 215.

10:09AM 2 THE COURT: THANK YOU. LET ME -- I DO WANT TO ASK

10:09AM 3 ABOUT WHAT THE STATUS OF THINGS ARE.

10:09AM 4 YOU INDICATED IN YOUR MOTION THAT THERE WAS TRAVEL BY

10:09AM 5 MR. BOSTIC, I THINK, YOURSELF AND MR. SCHENK TO WASHINGTON,

10:09AM 6 D.C. AND BALTIMORE IN EFFORTS TO DISCUSS MATTERS.

10:09AM 7 WHY DON'T YOU COME FORWARD AND UPDATE ME AND UPDATE US ON

10:09AM 8 THAT.

10:10AM 9 MR. LEACH: THANK YOU, YOUR HONOR. FIRST, LET ME

10:10AM 10 EXPLAIN A LITTLE BIT WHY YOU'RE HEARING FROM ME AND NOT

10:10AM 11 MR. BOSTIC WHO HAS BEEN LEADING THE CHARGE FOR THE GOVERNMENT

10:10AM 12 ON THIS PREVIOUSLY.

10:10AM 13 MR. BOSTIC WAS IN TRIAL AT THE TIME WHEN THE COURT ISSUED

10:10AM 14 ITS NOVEMBER 5TH ORDER. HE WAS APPEARING BEFORE JUDGE KOH, SO

10:10AM 15 AT THE TIME THE COURT RULED THAT THE GOVERNMENT HAD KNOWLEDGE

10:10AM 16 AND ACCESS TO THESE FDA DOCUMENTS. THE TASK FELL TO ME TO WORK

10:10AM 17 TO COMPLY WITH THAT ORDER AS EXPEDITIOUSLY AS POSSIBLE.

10:10AM 18 SO WE'RE ONE TEAM. WE HAVE THE SAME INFORMATION, BUT I AM

10:10AM 19 NOT JOHN BOSTIC, AND I JUST WANTED TO LET YOU KNOW WHY I'M

10:10AM 20 ADDRESSING THE COURT ON THESE ISSUES TODAY.

10:10AM 21 THE COURT: OKAY. WELL, THANK YOU.

10:10AM 22 MR. LEACH: WE ALSO HAVE ON THE PHONE, I JUST WANT

10:10AM 23 TO MAKE SURE THE COURT UNDERSTANDS, WE HAVE STACY AMIN, WHO IS

10:10AM 24 THE CHIEF COUNSEL FOR THE FOOD AND DRUG ADMINISTRATION, THE

10:10AM 25 SENIOR LAWYER FOR THE FDA, HER DEPUTY CHIEF COUNSEL,

10:10AM 1 PERHAM GORGİ, AND THE THREE ATTORNEYS STANDING BEHIND ME WHO I
10:11AM 2 HAVE INTRODUCED.

10:11AM 3 THEY'RE HERE TODAY TO underscore THE SERIOUSNESS WITH
10:11AM 4 WHICH THE FDA IS TAKING THIS ISSUE AND TO underscore THE
10:11AM 5 EFFORTS THAT THEY ARE TAKING TO COMPLY WITH THE COURT'S
10:11AM 6 NOVEMBER 5TH AND ITS PRIOR ORDERS.

10:11AM 7 AS I MENTIONED, SINCE THE NOVEMBER 5TH ORDER, YOUR HONOR,
10:11AM 8 THE GOVERNMENT HAS SPENT A SIGNIFICANT AMOUNT OF TIME WRESTLING
10:11AM 9 WITH THE QUESTION OF HOW TO GET THESE DOCUMENTS PRODUCED.

10:11AM 10 AS YOU ALLUDED TO, MR. SCHENK AND I TRAVELED BACK TO
10:11AM 11 WASHINGTON, D.C. TO MEET BOTH THE FDA, TO MEET WITH CMS TO COME
10:11AM 12 UP WITH A PLAN TO MAKE SURE THAT THESE DOCUMENTS ARE GETTING
10:11AM 13 PRODUCED.

10:11AM 14 AND AS PREPARING FOR THE HEARING TODAY, WHAT WAS STRIKING
10:11AM 15 TO ME IS THE AMOUNT OF COMMON GROUND THERE ACTUALLY IS WITH THE
10:11AM 16 PARTIES ON THIS ISSUE.

10:11AM 17 THE GOVERNMENT REQUESTED THESE DOCUMENTS BE PRODUCED
10:11AM 18 VOLUNTARILY. THE DEFENDANT REQUESTED THESE DOCUMENTS BE
10:11AM 19 PRODUCED. THE FDA IS SAYING THAT IT WANTS TO PRODUCE THESE
10:12AM 20 DOCUMENTS, AND THE ONLY ISSUE NOW IS A MECHANICAL ONE, I THINK,
10:12AM 21 HOW WE CAN GET THIS DATA AS QUICKLY AS WE CAN OUTSIDE OF THE
10:12AM 22 FDA TO THE DEFENDANTS.

10:12AM 23 THE COURT: SOME TIME BEFORE APRIL 30TH, IS THAT
10:12AM 24 WHAT YOU'RE GOING TO CONCLUDE?

10:12AM 25 MR. LEACH: THAT'S WHERE I'M GOING, YOUR HONOR.

10:12AM 1 THE COURT: GREAT.

10:12AM 2 MR. LEACH: AND I WANT TO EXPLAIN A LITTLE BIT ABOUT

10:12AM 3 WHY THAT IS THE CASE.

10:12AM 4 I THINK THE ISSUE HERE IS WITH -- THE COURT'S ORDER

10:12AM 5 REQUIRES ESSENTIALLY A RECOLLECTION OF DOCUMENTS BY THE FDA.

10:12AM 6 WHEN THE FDA STARTED TO PRODUCE DOCUMENTS IN RESPONSE TO

10:12AM 7 THE S.E.C. SUBPOENA IN THE S.E.C. CASE, AND THEN THE MOTION TO

10:12AM 8 COMPEL, FOR REASONS THAT I THINK ARE PERFECTLY DEFENSIBLE, IT

10:12AM 9 DID NOT INCLUDE THIS TERM CALLED LDT. THERE WAS GOOD REASON

10:12AM 10 FOR THAT. IT WASN'T LISTED IN THE SIX CATEGORIES. ALL OF THE

10:12AM 11 DOCUMENTS APPEAR TO BE RELATED TO THERANOS.

10:12AM 12 SO WHEN THEY WERE GOING TO THEIR CUSTODIANS AND COLLECTING

10:13AM 13 DOCUMENTS, THEY ARE NOT LOOKING FOR DOCUMENTS WITH THE TERM

10:13AM 14 LDT.

10:13AM 15 THEY WERE LOOKING FOR DOCUMENTS RELATING TO THERANOS.

10:13AM 16 THEY WERE LOOKING FOR DOCUMENTS RESPONSIVE TO THE SIX

10:13AM 17 CATEGORIES, BUT THIS TERM "LDT" WAS NOT SOMETHING THAT THEY

10:13AM 18 WERE LOOKING FOR IN THE FIRST INSTANCE.

10:13AM 19 THE COURT'S ORDER RESOLVED THAT ISSUE. WE ACKNOWLEDGED

10:13AM 20 THE COURT'S ORDER. WE ACKNOWLEDGE THESE DOCUMENTS ARE -- THAT

10:13AM 21 THE PROSECUTION OF KNOWLEDGE AND ACCESS TO THEM, BUT

10:13AM 22 ESSENTIALLY WHAT WE'VE BEEN DOING IS RECOLLECTING FROM OVER 88

10:13AM 23 CUSTODIANS TO TRY TO GET THE RIGHT UNIVERSE OF DOCUMENTS TO

10:13AM 24 MAKE SURE THAT THEY'RE BEING PRODUCED, AND THAT IS NO SMALL

10:13AM 25 FEAT, YOUR HONOR.

10:13AM 1 THAT REQUIRES, YOU KNOW, A TECHNICAL EXTRACTION FROM THE
10:13AM 2 FDA'S E-MAIL SYSTEM. THEY HAD A LIMITED LICENSE CAPACITY IN
10:13AM 3 ORDER TO DO THAT. THAT HAS BEEN FIXED, AND NOW THINGS ARE
10:13AM 4 MOVING A LITTLE BIT MORE QUICKLY.

10:13AM 5 IN ADDITION, WITH RESPECT TO NETWORK FILES, THERE'S A
10:13AM 6 PARTICULAR SOFTWARE THAT THE FDA USES THAT HAS ITS OWN LIMITS,
10:14AM 7 AND ON OUR TRIP BY MR. SCHENK AND BACK TO THE FDA WE ASKED,
10:14AM 8 WELL, ARE THERE RESOURCES THAT THE DOJ CAN GIVE TO HELP YOU
10:14AM 9 SOLVE THIS PROBLEM OR ARE THERE MORE PEOPLE THAT WE CAN SEND?

10:14AM 10 AND THE RESPONSE I'M GETTING IS NO, THAT THIS IS
10:14AM 11 COMPLICATED SOFTWARE, THAT IT REQUIRES A LENGTHY INSTALLATION
10:14AM 12 THAT IS INTEGRATED WITH THE FDA SYSTEM, THE FDA HAS ITS OWN
10:14AM 13 NETWORK CAPACITY.

10:14AM 14 AND I --

10:14AM 15 THE COURT: PARDON ME FOR INTERRUPTING YOU,
10:14AM 16 MR. LEACH.

10:14AM 17 SO YOU HAD OFFERED BODIES --

10:14AM 18 MR. LEACH: I DID, YOUR HONOR.

10:14AM 19 THE COURT: -- TO GO TO THE FDA AND ASSIST IN
10:14AM 20 CULLING THIS INFORMATION?

10:14AM 21 MR. LEACH: I DID, YOUR HONOR, YES.

10:14AM 22 THE COURT: OKAY. THANK YOU.

10:14AM 23 MR. LEACH: IN ADDITION, THE DOJ IS THROWING A LOT
10:14AM 24 OF BODIES, INCLUDING ME, INCLUDING MR. SCHENK, AND INCLUDING
10:14AM 25 MR. BOSTIC, AND ACTUALLY DOING SOME OF THE REVIEW OF THE DATA

10:14AM 1 THAT WE ARE GETTING FROM THE FDA.

10:14AM 2 SO I DON'T WANT TO STAND UP HERE AND LEAVE THE IMPRESSION

10:14AM 3 THAT THE DOJ IS NOT THROWING TREMENDOUS RESOURCES AT THIS. WE

10:15AM 4 ARE. BUT THERE ARE SOME TECHNICAL ISSUES AT THE HEART OF THIS

10:15AM 5 WHERE IN ORDER FOR DOJ TO REVIEW THIS, WE NEED TO EXTRACT IT

10:15AM 6 FROM THE E-MAIL SYSTEM USING THE TERMS THAT WERE NOW AGREED

10:15AM 7 UPON WITH THE DEFENSE. AND EVERY DAY I ASK THE QUESTION, WHY

10:15AM 8 CAN'T THAT GO FASTER? AND THE ANSWER, UNFORTUNATELY, IS SIMPLY

10:15AM 9 NOT ENOUGH LICENSES WITHIN THE FDA, INSTALLATION OF MORE WILL

10:15AM 10 TAKE A LOT OF TIME AND IS INTERTWINED WITH THE FDA NETWORK.

10:15AM 11 AND THERE JUST WAS NOT A GOOD TECHNOLOGICAL SOLUTION TO

10:15AM 12 THAT.

10:15AM 13 THE GOOD NEWS, YOUR HONOR, IS WE'VE RECEIVED -- DOJ HAS

10:15AM 14 RECEIVED THREE TRANCES OF DATA FROM FDA FROM THE E-MAIL

10:15AM 15 COLLECTION. I'VE LOST TRACK OF THE EXACT NUMBER OF CUSTODIANS,

10:15AM 16 BUT I THINK IT'S SOMEWHERE IN THE NEIGHBORHOOD OF 25 TO 30, AND

10:15AM 17 I THINK AN ADDITIONAL 10 WILL BE COMPLETED SOME TIME WITHIN THE

10:15AM 18 NEXT WEEK OR SO.

10:15AM 19 THERE'S ALSO NETWORK DATA THAT NEEDS TO BE EXTRACTED, AND

10:16AM 20 THERE'S ALSO THESE ARCHIVED CUSTODIANS THAT NEED TO BE RESTORED

10:16AM 21 AND THEN DELIVERED TO DOJ FOR REVIEW.

10:16AM 22 AND I WANT TO EMPHASIZE, THIS IS A RESULT OF IN PART

10:16AM 23 RE-COLLECTING FOR THIS TERM LDT, WHICH I THINK THE FDA HAD

10:16AM 24 DEFENSIBLE REASONS FOR NOT INCLUDING IN ITS INITIAL COLLECTION,

10:16AM 25 BUT WE ARE WHERE WE ARE ON THAT ISSUE, YOUR HONOR, AND THE

10:16AM 1 COURT HAS RULED ON IT AND WE'VE ACCEPTED THAT.

10:16AM 2 WE'RE TRYING AS QUICKLY AS WE CAN TO MAKE THAT

10:16AM 3 RE-COLLECTION HAPPEN AS QUICKLY AS IT CAN HAPPEN.

10:16AM 4 WE'VE PRODUCED OVER 130,000 DOCUMENTS TO THE DEFENDANTS

10:16AM 5 PRIOR TO -- ON DECEMBER 21ST, 2019, IN COMPLIANCE WITH THE

10:16AM 6 COURT'S ORDER. I NOW HAVE SOMETHING IN THE MAGNITUDE OF 400

10:16AM 7 GIGABYTES OF DATA AT THE DOJ THAT WE ARE LOOKING THROUGH AND

10:16AM 8 ANTICIPATING MAKING ANOTHER PRODUCTION IN THE NEXT WEEK OR TWO.

10:17AM 9 SO WE ARE MOVING JUST ABSOLUTELY AS FAST AS WE CAN. AND I

10:17AM 10 WANT TO EMPHASIZE THAT THERE IS AN ELEMENT OF DIMINISHING

10:17AM 11 RETURNS ON THESE DOCUMENTS THAT WE'RE PRODUCING. I DON'T WANT

10:17AM 12 TO MINIMIZE THE IMPORTANCE OF DOING THE SEARCH RIGHT, BECAUSE

10:17AM 13 WE ARE DOING THE SEARCH RIGHT.

10:17AM 14 BUT THERE ARE 88 CUSTODIANS THAT WE'RE LOOKING FOR HERE,

10:17AM 15 YOUR HONOR. A HANDFUL OF THESE WITNESSES AT BEST ARE EVER

10:17AM 16 GOING TO STEP FOOT IN THIS COURTROOM. IT IS NOT OUR INTENTION

10:17AM 17 TO DROP HUNDREDS OF THOUSANDS OF DOCUMENTS ON THE DEFENDANTS ON

10:17AM 18 APRIL 30TH. THAT IS NOT WHAT WE ARE TRYING TO DO.

10:17AM 19 WE ARE TRYING TO MOVE AS QUICKLY AS WE CAN AND BUILD IN A

10:17AM 20 REALISTIC TIMETABLE WHERE I HOPE BY APRIL 30TH, OR SHORTLY

10:17AM 21 AFTER THAT, IT'S THE LAST FEW CUSTODIANS THAT ARE COMING IN,

10:17AM 22 BUT THESE ARE NOT DOCUMENTS THAT HAVEN'T BEEN IN SOMEBODY

10:17AM 23 ELSE'S FILE OR SEEN SOMEWHERE ELSE, AND I AM NOT

10:17AM 24 REVOLUTIONIZING THE CASE FOR LACK OF A BETTER WORD.

10:17AM 25 BUT THAT'S WHAT WE'RE DOING.

10:18AM 1 THE DEFENSE RESPONSE TO THIS IS ESSENTIALLY MOVE FASTER,

10:18AM 2 AND THE GOVERNMENT HAS MET AND SPENT A LOT OF TIME TRYING TO

10:18AM 3 MAKE THIS MOVE AS QUICKLY AS WE CAN.

10:18AM 4 AS I HAVE EMPHASIZED, WE HAVE ALREADY PRODUCED 130,000

10:18AM 5 DOCUMENTS BETWEEN NOVEMBER 5TH AND DECEMBER 31ST.

10:18AM 6 THE COURT: APPARENTLY THEY'RE SPEED READERS AND

10:18AM 7 THEY FINISHED GOING THROUGH THAT AND THEY NEED MORE WORK.

10:18AM 8 MR. LEACH: I'M DOING WHAT I CAN THERE.

10:18AM 9 THE COURT: WE'LL HEAR FROM THEM A MOMENT.

10:18AM 10 I APPRECIATE THAT. BUT YOU ALSO INDICATE IN YOUR

10:18AM 11 PLEADINGS THAT IN AN EFFORT TO GAIN EFFICIENCY IN THE

10:18AM 12 PRODUCTION, YOU HAVE WORKED, I THINK, WITH THE DEFENSE TO

10:18AM 13 IDENTIFY MORE CRITICAL WITNESSES AND INFORMATION AND YOU HAVE

10:18AM 14 FOCUSSSED ON ACCOMPLISHING AND RELEASING THAT IN A PRIORITY TYPE

10:18AM 15 OF MANNER.

10:18AM 16 MR. LEACH: I THINK QUITE COLLABORATIVELY, YOUR

10:18AM 17 HONOR. I'LL LET THEM SPEAK TO THAT. BUT THERE'S AGREEMENT ON

10:18AM 18 THE TERMS THAT SHOULD BE USED TO DO THIS RE-COLLECTION.

10:19AM 19 THE DEFENSE HAS AGREED TO AN ORDER REQUIRING THE FDA TO

10:19AM 20 PRODUCE CERTAIN DOCUMENTS AND NOTWITHSTANDING STATUTORY

10:19AM 21 PROHIBITIONS ON US DOING THAT; AND, THEREFORE, ENABLING THE DOJ

10:19AM 22 TO CONDUCT THE REVIEW. SO I THINK THERE HAS BEEN COLLABORATION

10:19AM 23 ON THAT.

10:19AM 24 I WOULD ALSO EMPHASIZE THAT THEY VERY HELPFULLY GAVE US A

10:19AM 25 LIST OF THE 22 MOST IMPORTANT CUSTODIANS IN THEIR MIND, AND WE

10:19AM 1 HAVE PRIORITIZED THOSE. I THINK THE E-MAIL FILES FOR ALL OF
10:19AM 2 THE ACTIVE ONES ARE AT LEAST NOW IN DOJ'S POSSESSION AND WILL
10:19AM 3 BE GOING OUT SHORTLY.

10:19AM 4 THE COURT: SO GOING OUT SHORTLY MEANING YOU'LL BE
10:19AM 5 ABLE TO RELEASE THOSE 22?

10:19AM 6 MR. LEACH: I NEED TO BE CAREFUL, YOUR HONOR,
10:19AM 7 BECAUSE THERE ARE SOME FORMER EMPLOYEES THAT I DON'T THINK I
10:19AM 8 HAVE YET. WHEN I SIT DOWN I CAN CHECK ON THAT DETAIL.

10:19AM 9 BUT IF THEY'RE A CURRENT FDA EMPLOYEE, WE WILL HAVE ALL OF
10:19AM 10 THE E-MAIL DATA. IF I DON'T ALREADY HAVE IT, IT'S GOING TO BE
10:19AM 11 THIS WEEK, AND THAT WILL BE GOING OUT VERY SHORTLY.

10:19AM 12 THE COURT: TO THEM?

10:19AM 13 MR. LEACH: YES. OH, YES.

10:19AM 14 THE COURT: SO LET ME ASK YOU A LARGE OVERARCHING
10:20AM 15 QUESTION PERHAPS, WHICH IS IF WE WAIT UNTIL APRIL 30TH, THE
10:20AM 16 COURT SAYS I APPRECIATE YOUR EFFORTS, AND I DO, LET ME JUST SAY
10:20AM 17 THAT, I DO APPRECIATE. SENDING LAWYERS OUT TO WASHINGTON, D.C.
10:20AM 18 IN JANUARY IS A REMARKABLE THING TO DO. AND YOU'VE MET YOUR
10:20AM 19 DECLARATION.

10:20AM 20 YOUR BRIEFING TELLS US THAT YOU'VE MET IN BALTIMORE AND IN
10:20AM 21 WASHINGTON, D.C. WITH THE APPROPRIATE PARTIES. MY SENSE IS
10:20AM 22 THAT YOU'VE URGED THEM, YOU'VE EXPRESSED THE URGENCY OF THIS
10:20AM 23 COURT'S ORDER AND WHAT THAT MEANS AND THE NEED FOR THIS
10:20AM 24 INFORMATION FOR THIS PARTICULAR LITIGATION.

10:20AM 25 MY QUESTION IS IF WE WAIT UNTIL APRIL 30TH, WHAT IS YOUR

10:20AM 1 POSITION ON WHETHER OR NOT THAT WILL DISTURB THE TRIAL DATE?

10:20AM 2 MR. BOSTIC: IT WILL NOT DISTURB THE TRIAL DATE FROM

10:20AM 3 THE GOVERNMENT'S PERSPECTIVE, YOUR HONOR. WE ARE NOT ASKING

10:20AM 4 FOR MORE TIME.

10:20AM 5 THESE ARE NOT DOCUMENTS THAT THE GOVERNMENT EXPECTS TO BE

10:21AM 6 USING IN ITS CASE-IN-CHIEF, AND WE WILL BE PREPARED TO HAVE

10:21AM 7 REVIEWED THEM AND DIGESTED THEM WITHIN THE TIME ALLOTTED FOR

10:21AM 8 THE TRIAL DATE. I DON'T KNOW WHAT THE DEFENSE'S POSITION IS.

10:21AM 9 THE COURT: WELL, YOU CAN ANTICIPATE THAT THEY'RE

10:21AM 10 GOING TO SAY THAT GIVES US 90 DAYS TO GO THROUGH WHATEVER

10:21AM 11 TERABYTES THIS INFORMATION IS, AND WE CAN'T POSSIBLY DO THAT.

10:21AM 12 AND THEY'LL START TALKING ABOUT THE CONSTITUTION AND THE

10:21AM 13 SIXTH AMENDMENT AND THE FIFTH AMENDMENT AND OTHERS. AND

10:21AM 14 THEY'LL SAY, JUDGE, WE NEED MORE TIME TO GO THROUGH THIS. IT'S

10:21AM 15 NOT FAIR TO UNLOAD THIS WHEELBARROW OF INFORMATION ON US WHILE

10:21AM 16 WE'RE TRYING TO PREPARE.

10:21AM 17 BUT WHAT YOU'VE SAID IS THAT'S NOT WHAT'S HAPPENING. IT

10:21AM 18 SOUNDS LIKE THERE'S A ROLLING RELEASE OF INFORMATION AND THE

10:21AM 19 INFORMATION THAT THEY'RE GETTING IS SUFFICIENT FOR THEM TO

10:21AM 20 REVIEW NOW.

10:21AM 21 IF YOU GAVE THEM A WHOLE DUMP TRUCK OF INFORMATION NOW, IT

10:21AM 22 WOULD PROBABLY TAKE THEM BEYOND APRIL 30TH JUST TO READ IT MY

10:21AM 23 SENSE IS.

10:22AM 24 MR. LEACH: IT ABSOLUTELY IS A ROLLING PRODUCTION,

10:22AM 25 YOUR HONOR. THE POINT I WOULD LIKE TO MAKE THERE IS THIS IS

10:22AM 1 NOT A SITUATION WHERE IT'S ANYBODY'S INTENTION TO WAIT UNTIL
10:22AM 2 APRIL 30TH AND SAY, HERE YOU GO, THIS IS THE UNIVERSE OF FDA
10:22AM 3 DOCUMENTS, REVIEW THEM.

10:22AM 4 WE'RE GETTING AS MUCH AS WE CAN TO THEM AS QUICKLY AS WE
10:22AM 5 CAN TO THEM.

10:22AM 6 BUT WHEN YOU ASK ME WHEN CAN I BE DONE REVIEWING THE FILES
10:22AM 7 OF 88 CUSTODIANS AND GOING THROUGH ALL OF THE MECHANICAL ISSUES
10:22AM 8 THAT WE HAVE TO GO THROUGH TO EXTRACT THAT DATA, GET IT TO DOJ,
10:22AM 9 GET THE REVIEW DONE, THE BEST I CAN PROMISE ON THAT IS
10:22AM 10 APRIL 30TH.

10:22AM 11 BUT IT IS NOT OUR INTENTION AT ALL TO WAIT UNTIL THEN TO
10:22AM 12 PRODUCE AS LARGE A CHUNK AS WE CAN.

10:22AM 13 THE COURT: OKAY. TELL ME WHAT YOU MEAN BY "A
10:22AM 14 MANUAL SEARCH" FOR MARGINALLY RELEVANT CUSTODIANS?

10:22AM 15 IS THERE A DISCUSSION OR DISPUTE ABOUT A MANUAL SEARCH AS
10:23AM 16 OPPOSED TO AN ELECTRONIC OR OTHER SEARCH?

10:23AM 17 MR. LEACH: WHAT I MEAN BY THAT, YOUR HONOR, IS IT'S
10:23AM 18 A SELF-COLLECTION. SO WHAT THE GOVERNMENT'S INTENTION WITH
10:23AM 19 THOSE 23 INDIVIDUALS IS THAT WE WOULD GIVE THEM THE 6
10:23AM 20 CATEGORIES OF DOCUMENTS, WE WOULD GIVE THEM A LIST OF SEARCH
10:23AM 21 TERMS. THOSE SEARCH TERMS WOULD INCLUDE THERANOS, LTD,
10:23AM 22 FRANKLY, WHATEVER THE DEFENSE WANTS TO INCLUDE ON THAT AND HAS
10:23AM 23 INCLUDED ON THAT, AND WE WOULD ASK THOSE CUSTODIANS TO PERFORM
10:23AM 24 THE SEARCH ON THEIR COMPUTER, SO GO INTO YOUR E-MAIL FILE AND
10:23AM 25 LOOK FOR THE WORD "THERANOS."

10:23AM 1 IF YOU HAVE AN E-MAIL FILE FOR THERANOS, COPY THAT TO THIS
10:23AM 2 DRIVE SO THE I.T. PROFESSIONALS CAN PROCESS THAT.

10:23AM 3 THE COURT: AND THIS WOULD BE SUPERVISED BY DOJ
10:23AM 4 INDIVIDUALS?

10:23AM 5 MR. LEACH: DOJ -- WE WILL DO WHATEVER THE COURT
10:23AM 6 REQUIRES OF US ON THAT POINT, AND I THINK THERE'S SOME, YOU
10:23AM 7 KNOW, WE'RE NOT -- WE HAVE ACCESS AND KNOWLEDGE OF THESE
10:24AM 8 DOCUMENTS. I'M NOT HERE TO SAY ANYTHING OTHERWISE.

10:24AM 9 BUT I DON'T WORK IN THE FDA. WHEN I GO TO THE FDA, YOUR
10:24AM 10 HONOR, I WALK THROUGH THE SECURITY GATE JUST LIKE ANYBODY ELSE.
10:24AM 11 THEY'RE STATUTORILY PROHIBITED FROM GIVING ME ACCESS TO CERTAIN
10:24AM 12 INFORMATION, AND SO I WILL NOT BE SITTING OVER THE COMPUTER AS
10:24AM 13 SOMEBODY DOES THAT, BUT DOJ WILL HAVE SIGNIFICANT INPUT ON THE
10:24AM 14 SCRIPT OR THE INSTRUCTIONS OR THE DIRECTION THAT THEY WILL BE
10:24AM 15 GIVEN.

10:24AM 16 AND I NEED TO EMPHASIZE, HALF OF THIS GROUP IS LAWYERS WHO
10:24AM 17 ARE AS CAPABLE, IF NOT MORE CAPABLE, THAN ME FOR FINDING THESE
10:24AM 18 DOCUMENTS.

10:24AM 19 I REALLY THINK THAT IN THE DIALOGUE THAT WE WERE HAVING
10:24AM 20 BEFORE ABOUT DEFICIENCIES IN THE SEARCH, YOU KNOW, I HAVE NO
10:24AM 21 REASON TO THINK THAT THESE LAWYERS AREN'T PERFECTLY CAPABLE OF
10:24AM 22 FINDING THE RESPONSIVE DOCUMENTS WITH VERY PRECISE DIRECTIONS
10:24AM 23 FROM DOJ, SOMETHING IN WRITING, AND SO THAT'S WHAT WE MEAN BY
10:24AM 24 SELF-COLLECTION AS OPPOSED TO THE ELECTRONIC COLLECTION, WHICH
10:25AM 25 WE'VE BEEN DOING, WHERE THE FDA'S I.T. TEAM IS GOING INTO

10:25AM 1 OUTLOOK THEMSELVES, RUNNING THE SEARCH TERMS THEMSELVES, TAKING
10:25AM 2 THAT DATA, AND GIVING IT TO DOJ.

10:25AM 3 SO THERE'S NO REAL JUDGMENT IN ANY OF THAT. BUT THE
10:25AM 4 SELF-COLLECTION IS, FOR EXAMPLE, IF I GIVE ONE SHEET OF
10:25AM 5 INSTRUCTIONS TO YOUR HONOR TO GO BACK TO YOUR CHAMBERS AND LOOK
10:25AM 6 FOR YOUR THERANOS FILE, AND PUT IT HERE, THAT'S WHAT WE MEAN BY
10:25AM 7 SELF-COLLECTION.

10:25AM 8 THE COURT: ARE YOU SUGGESTING THAT THAT WILL
10:25AM 9 EXPEDITE THE MANUAL SELF-SELECTION? WILL THAT BE QUICKER OR
10:25AM 10 WILL THAT BE FASTER THAN THE ELECTRONIC VERSION, OR IS THAT IN
10:25AM 11 ADDITION TO?

10:25AM 12 MR. LEACH: IT WILL BE QUICKER, IT WILL BE FASTER,
10:25AM 13 BUT THAT THE -- THAT WITH ELECTRONIC COLLECTION IS STILL GOING
10:25AM 14 TO TAKE TO BE DONE, DONE, APRIL 30TH.

10:25AM 15 IF THE COURT REQUIRES US TO DO SOMETHING DIFFERENT FOR
10:26AM 16 THOSE 23, WE'RE LOOKING AT A TIMEFRAME THAT IS EVEN LONGER.

10:26AM 17 THE COURT: I SEE.

10:26AM 18 SO THE QUESTION THAT A PERSON MIGHT ASK IS, WELL, THAT'S
10:26AM 19 FINE, YOU CAN ASK PEOPLE TO GO TO THEIR COMPUTERS AND DO THIS,
10:26AM 20 BUT HOW DO WE KNOW? HOW DO WE VERIFY THAT THEY'RE ACTUALLY
10:26AM 21 DOING THAT?

10:26AM 22 IF A FILE COMES UP AND IT'S SOMETHING THAT THEY MISS OR
10:26AM 23 THEY MIGHT HAVE SOME QUALMS ABOUT, HOW DO WE KNOW WE'RE GETTING
10:26AM 24 EVERYTHING?

10:26AM 25 I EXPECT THE DEFENSE MIGHT SAY THERE'S NO ASSURANCE AS FAR

10:26AM 1 AS -- WE'RE JUST RELYING ON THE INDIVIDUAL AS OPPOSED TO AN
10:26AM 2 ACTUAL REAL ELECTRONIC RECORD OF WHAT WAS DONE.

10:26AM 3 MR. LEACH: THOSE ARE PROBLEMS THAT ARE INHERENT IN
10:26AM 4 ANY DOCUMENT COLLECTION BY ANYBODY.

10:26AM 5 IF YOU HAVE A CLIENT, YOUR HONOR, AND YOU SAY -- THE
10:26AM 6 RELATIONSHIP BETWEEN ME AND THE FDA IS DIFFERENT THAN THIS, BUT
10:26AM 7 I'M USING THIS AS A HYPOTHETICAL FOR YOU.

10:26AM 8 YOU KNOW, IF YOU SAY THE OTHER SIDE HAS ASKED FOR THESE
10:26AM 9 FIVE DOCUMENTS, I NEED TO GO LOOK THROUGH YOUR FILES TO FIND
10:27AM 10 THIS, AND THEY SHOW YOU THE FILES, BUT THEN THEY REMEMBER THAT
10:27AM 11 THEY HAVE SOME IN THE GARAGE, LIKE ALL OF THIS IS INHERENTLY
10:27AM 12 DEPENDENT ON SOME INDIVIDUAL AT THE END OF THE DAY RECEIVING
10:27AM 13 THIS REQUEST.

10:27AM 14 BUT I'M CONFIDENT ABOUT WHAT THE GOVERNMENT'S RULE 16
10:27AM 15 OBLIGATION IS THAT IF, WITH THE HELP OF THE DEFENSE WITH THE
10:27AM 16 FDA'S I.T. PROFESSIONALS, THE FACT THAT THESE ARE VERY
10:27AM 17 SOPHISTICATED LAWYERS WORKING WITHIN THE OFFICE OF CHIEF
10:27AM 18 COUNSEL, IF I SAY GO LOOK HERE, GO LOOK THERE, RUN THESE
10:27AM 19 SEARCHES, NO DISCRETION IN THE SEARCH TERMS, NO DISCRETION IN
10:27AM 20 WHERE THEY'RE WORKING, THE LIKELIHOOD OF A MATERIAL DOCUMENT
10:27AM 21 BEING MISSED GOES WAY, WAY DOWN.

10:27AM 22 SO, YOU KNOW, NO SYSTEM IS PERFECT, YOUR HONOR.

10:27AM 23 THE COURT: SURE. EVERYTHING IS SUBJECT TO HUMAN
10:27AM 24 FOIBLE.

10:27AM 25 BUT I'M JUST CURIOUS, AND I'LL ASK THE DEFENSE ABOUT THIS,

10:27AM 1 IT MAY BE THAT THIS COURT -- AND I'LL ASK MS. AMIN HER OPINION

10:27AM 2 ABOUT THIS AS WELL -- IT MAY BE THAT THE COURT COULD HAVE THAT

10:28AM 3 GO FORWARD, THAT MANUAL SEARCH GO FORWARD WITH THIS COURT'S

10:28AM 4 ORDER TO THE ATTORNEYS WHO ARE DOING THE SEARCH TO DO CERTAIN

10:28AM 5 THINGS TO MAKE SURE THAT THEY TURN OVER EVERY DOCUMENT, NO

10:28AM 6 QUESTION ABOUT IT.

10:28AM 7 IN OTHER WORDS, THERE'S NO -- HOW SHALL I SAY? -- JUDGMENT

10:28AM 8 INVOLVED. IT'S THEY ARE PUSH THE BUTTON, AND PUSH PRINT, OR

10:28AM 9 WHATEVER IT IS, AND THAT'S IT, AND THEY HAVE NO DISCRETION ON

10:28AM 10 THAT.

10:28AM 11 DO YOU THINK YOU AND YOUR COLLEAGUE OPPOSITES COULD COME

10:28AM 12 UP WITH AN ORDER THAT MIGHT SATISFY MS. AMIN, AND MS. NORTON,

10:28AM 13 AND MS. MARTINEZ-RESLY, AND MR. WEINFIELD ABOUT THOSE THINGS?

10:28AM 14 MR. LEACH: YES, YOUR HONOR.

10:28AM 15 THE COURT: OKAY.

10:28AM 16 MR. LEACH: BEFORE I PASS THE MIKE, YOUR HONOR, WE

10:28AM 17 DID INVITE THE CHIEF COUNSEL FROM THE FDA TO BE PRESENT FOR

10:28AM 18 THIS HEARING. SHE WANTED VERY MUCH TO BE HERE IN PERSON, BUT

10:28AM 19 SOME OTHER VERY IMPORTANT DEMANDS GOT IN THE WAY.

10:28AM 20 BUT I DO THINK IT'S IMPORTANT THAT THE COURT HEAR DIRECTLY

10:28AM 21 FROM MS. AMIN --

10:29AM 22 THE COURT: SURE.

10:29AM 23 MR. LEACH: -- ABOUT THE EFFORTS THAT THE FDA IS

10:29AM 24 TAKING.

10:29AM 25 THE COURT: WELL, THANK YOU. I'M HAPPY TO DO THAT.

10:29AM 1 MS. AMIN, THANK YOU FOR JOINING US TELEPHONICALLY. YOU'VE
10:29AM 2 HEARD OUR DISCUSSION AND SOME OF THE QUESTIONS THAT I'VE HAD.
10:29AM 3 I'M HAPPY TO HEAR FROM YOU NOW IF YOU WOULD LIKE TO SHARE ANY
10:29AM 4 ITEM WITH US.

10:29AM 5 MS. AMIN: YOUR HONOR, THANK YOU TO GIVING ME THE
10:29AM 6 OPPORTUNITY TO ADDRESS THE COURT. AND I WANT TO ASSURE YOU
10:29AM 7 THAT THE FDA IS MAKING EXTRAORDINARY EFFORTS TO COMPLY WITH THE
10:29AM 8 DOCUMENT PRODUCTION SCHEDULE.

10:29AM 9 THIS IS AN UNPRECEDENTED SITUATION FOR THE FDA. WE HAVE
10:29AM 10 NEVER BEFORE BEEN SUBJECT TO A DOCUMENT PRODUCTION OF THIS
10:29AM 11 SCOPE ON THIS TIMEFRAME WHERE WE'RE PRODUCING HUNDREDS OF
10:29AM 12 THOUSANDS OF PAGES OF DOCUMENTS IN A MATTER OF MONTHS, AND MANY
10:29AM 13 OF THOSE DOCUMENTS DETAIL SENSITIVE AGENCY DELIBERATIONS AND
10:29AM 14 CONFIDENTIAL AND COMMERCIAL TRADE SECRET INFORMATION PROTECTED
10:29AM 15 BY STATUTE.

10:29AM 16 SO IT'S BEEN VERY CHALLENGING AND UNPRECEDENTED THE
10:29AM 17 SITUATION THAT WE ARE TASKED WITH.

10:30AM 18 AND I WANT TO ASSURE YOU THAT THE LEADERSHIP AT THE
10:30AM 19 AGENCY, ACROSS THE WHOLE AGENCY AND AT THE HIGHEST LEVEL OF THE
10:30AM 20 AGENCY ARE ENGAGED IN REGULAR DISCUSSIONS ABOUT HOW TO COMPLY
10:30AM 21 WITH THE COURT'S SCHEDULE.

10:30AM 22 WE HAVE DEDICATED CAREER CIVIL SERVANTS THAT ARE WORKING
10:30AM 23 200 PERCENT OF THEIR NORMAL CAPACITY ON THIS, AND WE HAVE
10:30AM 24 DIVERTED STAFF AND RESOURCES AWAY FROM OTHER HIGH MAJORITY
10:30AM 25 MISSIONS, SUPPORTIVE TASKS, INCLUDING CRIMINAL INVESTIGATIONS,

10:30AM 1 INJUNCTION REFERRALS, WARNING LETTERS AS EXAMPLES. I CAN'T GET
10:30AM 2 INTO SPECIFIC PROJECTS, BUT IT'S THE KIND OF WORK THAT SUPPORTS
10:30AM 3 OUR CRITICAL PUBLIC HEALTH MISSION TO ENSURE THE SAFETY OF THE
10:30AM 4 FOOD WE EAT AND THE MEDICAL PRODUCTS THAT WE USE, AND SOME OF
10:30AM 5 THAT WORK HAS TAKEN A BACK SEAT TO THIS DISCOVERY, AND I JUST
10:30AM 6 TELL YOU THAT TO ILLUSTRATE HOW SERIOUSLY WE ARE TAKING THIS
10:30AM 7 AND HOW HARD WE ARE TRYING TO MEET THE SCHEDULE.
10:30AM 8 BUT EVEN DESPITE THE EXTRA STAFF AND RESOURCES THAT WE
10:30AM 9 HAVE DEVOTED AND WE HAVE TAKEN ADVANTAGE OF EVERY OFFER OF
10:31AM 10 SUPPORT AND RESOURCES THAT DOJ HAS PROVIDED THAT WOULD HELP
10:31AM 11 SPEED THE PROCESS ALONG, EVEN WITH ALL OF THAT, THERE ARE
10:31AM 12 TECHNICAL LIMITATIONS TO WHAT WE CAN DO.
10:31AM 13 AND I CAN GO INTO MORE DETAIL ABOUT WHAT THOSE TECHNICAL
10:31AM 14 LIMITATIONS ARE. THE GOVERNMENT'S COUNSEL HAS HIGHLIGHTED A
10:31AM 15 FEW OF THEM, BUT I CAN GET INTO MORE DETAIL, AND THERE ARE
10:31AM 16 REALLY THREE MAJOR LIMITATIONS.
10:31AM 17 FIRST, OUR SOFTWARE HAS LIMITATIONS FOR DOCUMENTS FROM
10:31AM 18 NETWORK DRIVES. FDA MUST USE THE NK SOFTWARE TO COLLECT,
10:31AM 19 SEARCH, AND EXPORT THOSE DOCUMENTS AND NK'S CONTRACTORS MUST
10:31AM 20 HAVE THE SOFTWARE INSTALLED AND BE LICENSED AND TRAINED TO USE
10:31AM 21 IT.
10:31AM 22 FDA HAS TWO NK LICENSE FOR LITIGATION AND COMPLIANCE. AND
10:31AM 23 WHAT WE HAVE FOUND IS THAT THE SOFTWARE IS PROHIBITIVELY SLOW
10:31AM 24 WHEN RUNNING SEARCH STRINGS AT THE SAME TIME THAT WE ARE
10:31AM 25 COLLECTING.

10:31AM 1 OUR I.T. STAFF BELIEVES IT WOULD TAKE TOO MUCH TIME TO
10:31AM 2 ONBOARD AND TRAIN MORE CONTRACTORS WITHIN THE TIMEFRAME THAT
10:31AM 3 THIS DISCOVERY NEEDS TO OCCUR, SO WE HAVE ADDRESSED THIS
10:32AM 4 LIMITATION BY EXPORTING DOCUMENTS WITHOUT CONCURRENTLY RUNNING
10:32AM 5 THE SEARCH TERMS, AND INSTEAD DOJ IS NOW GETTING THE NATIVE
10:32AM 6 FILES THEMSELVES AND RUNNING THE SEARCHES THEMSELVES.
10:32AM 7 AS THE GOVERNMENT COUNSEL JUST EXPLAINED, FOR A SET OF
10:32AM 8 CUSTODIANS WILL BE SELF-COLLECTING SO THAT WE CAN CONCURRENTLY
10:32AM 9 DO BOTH SETS AT THE SAME TIME.
10:32AM 10 SIMILARLY, WE HAVE LIMITATIONS WITH OUR CONTRACT WITH
10:32AM 11 MICROSOFT OR OUTLOOK 365 WHICH LIMITED HOW MUCH DATA A DAY WE
10:32AM 12 COULD DOWNLOAD AND HOW MANY CONCURRENT SEARCHES WE COULD RUN.
10:32AM 13 BUT REALLY THE BIGGEST PROBLEM IN OUTLOOK 365 WERE THE
10:32AM 14 ERRORS THAT OCCUR WHEN WE PERFORM CONCURRENT SEARCHES. SO WE
10:32AM 15 ARE NO LONGER PERFORMING SEARCHES IN OUTLOOK AND AS INSTEAD, AS
10:32AM 16 WAS MENTIONED, WE'RE GIVING DOJ THE NATIVE FILES AND DOJ IS
10:32AM 17 RUNNING THE SEARCHES, AND MY UNDERSTANDING IS THAT THEY ARE
10:33AM 18 PUTTING A SIGNIFICANT AMOUNT OF RESOURCES INTO THAT.
10:33AM 19 AND WE HAVE ALSO ADDRESSED OUR DOWNLOAD LIMITATIONS BY
10:33AM 20 INCREASING OUR CAPACITY WITH MICROSOFT. ALL OF THAT HAS TAKEN
10:33AM 21 TIME TO DO.
10:33AM 22 THE SECOND MAJOR LIMITATION IS OUR NETWORK BANDWIDTH,
10:33AM 23 WHICH LIMITS HOW MUCH DATA CAN BE EXPORTED AT ANY GIVEN TIME.
10:33AM 24 WHILE WE CONTINUE TO EXAMINE THE CAUSES OF ANY LIMITATIONS
10:33AM 25 THAT WE HAVE, WE'VE FOUND THAT AS WE HAVE IMPROVED THE

10:33AM 1 EFFICIENCY OF OUR SOFTWARE AND WE CAN MANAGE MORE DOWNLOADS AT
10:33AM 2 A TIME THROUGH THAT SOFTWARE, WE BELIEVE OUR NETWORK MAY BE
10:33AM 3 LIMITING HOW MUCH DATA WE CAN EXPORT IN A DAY. OUR NETWORK HAS
10:33AM 4 TO MANAGE ALL OF THE AGENCY'S TRAFFIC, AND THERE ARE LIMITS ON
10:33AM 5 HOW MUCH TOTAL TRAFFIC IT CAN ACCOMMODATE BEFORE NETWORK
10:33AM 6 FUNCTIONS ARE DISRUPTED.

10:33AM 7 SO AT THE HIGHEST LEVEL OF THE AGENCY WE ARE COMMITTED TO
10:33AM 8 ADDRESSING THIS ISSUE SO THAT GOING FORWARD WE ARE NEVER IN
10:33AM 9 THIS POSITION AGAIN OF NOT BEING ABLE TO MEET A COURT ORDERED
10:33AM 10 DEADLINE.

10:33AM 11 THE ADDING NETWORK CAPACITY IS SOMETHING THAT OUR
10:34AM 12 TECHNICAL EXPERTS HAVE SAID IT CAN'T BE DONE OVERNIGHT OR EVEN
10:34AM 13 IN A MATTER OF MONTHS. IT'S A MAJOR ENDEAVOR THAT I'VE BEEN
10:34AM 14 TOLD CAN TAKE 12 TO 18 MONTHS. SO WE'RE WORKING TOWARDS THAT
10:34AM 15 LONG-TERM SOLUTION, BUT IT'S NOT SOMETHING THAT RIGHT NOW ANY
10:34AM 16 MONEY OR PEOPLE CAN FIX.

10:34AM 17 SO WHAT WE'RE DOING IN THE MEANTIME IS ADDRESSING THIS, AS
10:34AM 18 THE GOVERNMENT'S COUNSEL EXPLAINED, CONCURRENTLY HAVING LOWER
10:34AM 19 PRIORITY CUSTODIANS MANUALLY PULL THEIR RESPONSIVE DOCUMENTS,
10:34AM 20 AND I CAN PROVIDE A LITTLE BIT MORE DETAIL ABOUT OUR PLAN FOR
10:34AM 21 DOING THIS. THIS WILL BE DONE IN ACCORDANCE WITH A
10:34AM 22 SUBCOLLECTION PROTOCOL THAT WILL BE DEVELOPED BY FDA AND DOJ
10:34AM 23 TOGETHER.

10:34AM 24 WE WILL HAVE AN ATTORNEY FROM FDA WHO WILL LEAD THIS
10:34AM 25 PROCESS FOR THE AGENCY, AND WE'LL HAVE A TEAM STAFFED BY FOUR

10:34AM 1 OTHER ATTORNEYS AND OTHER COMPLIANCE PROFESSIONALS IN THE
10:34AM 2 AGENCY, AND THIS TEAM WILL HAND HOLD CUSTODIANS THROUGH THE
10:34AM 3 PROCESS OF THE MANUAL DOCUMENT COLLECTION SO THAT THEY'RE DONE
10:34AM 4 IN ACCORDANCE WITH THE PROTOCOL.

10:34AM 5 I CAN TELL YOU THAT THIS IS SOMETHING THAT THE AGENCY HAS
10:35AM 6 NEVER DONE BEFORE, AND FOR MANY DECADES THE WAY THAT WE
10:35AM 7 RESPONDED TO SUBPOENAS AND OVERSIGHT REQUESTS AND FOIA AND
10:35AM 8 DISCOVERY LITIGATION WAS THROUGH MANUAL COLLECTION, AND THIS IS
10:35AM 9 AN EXTRA LAYER OF ASSURANCE THAT WE'LL PROVIDE THE PROCESS BY
10:35AM 10 HAVING THAT TEAM HAND HOLD THE CUSTODIANS.

10:35AM 11 AND AS THE GOVERNMENT'S COUNSEL SAID, TEN OF THOSE
10:35AM 12 CUSTODIANS ARE ATTORNEYS IN THE OFFICE OF CHIEF COUNSEL WHO
10:35AM 13 ARE, YOU KNOW, BARRED AND PRACTICING ATTORNEYS.

10:35AM 14 I CAN SURELY TELL YOU THEY CAN BE TRUSTED TO DO IT
10:35AM 15 ACCURATELY AND CORRECTLY.

10:35AM 16 SO THE THIRD CHALLENGE THAT WE HAVE HAD ARE WITH ARCHIVED
10:35AM 17 DOCUMENTS, AND THOSE ARE FROM FORMER EMPLOYEES. THEY POSE
10:35AM 18 SIGNIFICANT TECHNICAL CHALLENGES FOR US. THE FILES ARE
10:35AM 19 COMPRESSED TO SAVE STORAGE, SO THEY HAVE TO BE DECOMPRESSED TO
10:35AM 20 BE READABLE, AND THAT HAS BEEN A RESOURCE INTENSIVE PROCESS.

10:35AM 21 AND ALSO THE WAY THE FILES ARE ARCHIVED, THEY LOSE THEIR
10:36AM 22 ATTACHMENTS IN THE ARCHIVING PROCESS SO THEY HAVE TO GO THROUGH
10:36AM 23 A PROCESS THAT IS CALLED REHYDRATION TO ENSURE THAT THE E-MAILS
10:36AM 24 ARE MATCHED WITH THEIR ATTACHMENT.

10:36AM 25 THE FDA IS USING A SOFTWARE CALLED SOURCE ONE FOR THIS

10:36AM 1 PROCESS. WE HAVE FOUND THAT THE SOURCE ONE SOFTWARE MAKES A
10:36AM 2 BIG DIFFERENCE HOW MUCH EXPERIENCE PEOPLE HAVE WITH THE
10:36AM 3 SOFTWARE AND HOW QUICKLY THEY CAN USE IT, AND THAT EXPERIENCE
10:36AM 4 IS SOMETHING THAT CAN'T HAPPEN OVERNIGHT, BUT WE HAVE DIVERTED
10:36AM 5 STAFF TO WORK WITH THE SOFTWARE AND TO GET TRAINED WHILE USING
10:36AM 6 IT.

10:36AM 7 WE HAVE ALSO UPGRADED THE PROCESSING AND MEMORY ON THE
10:36AM 8 SOURCE ONE SERVERS WHICH WAS EFFECTIVE AT THE END OF DECEMBER,
10:36AM 9 AND LAST WEEK WE COMPLETED A STORAGE CAPACITY UPGRADE, AND
10:36AM 10 WE'RE ALSO UPGRADING THE SOURCE ONE SOFTWARE THAT WILL BE
10:36AM 11 COMPLETE BY THE END OF JANUARY.

10:36AM 12 AND I CAN TELL YOU THAT OUR I.T. STAFF IS VERY EXCITED
10:36AM 13 ABOUT ALL OF THESE ENHANCEMENTS WE HAVE MADE AND UPGRADES THAT
10:36AM 14 WE ARE MAKING, AND THEY BELIEVE IT WILL PROVIDE ADDITIONAL
10:37AM 15 CAPACITY AND EFFICIENCY.

10:37AM 16 AGAIN, WITH THESE FILES, AS WITH THE OTHER FILES, WE'RE
10:37AM 17 GOING TO GIVE THE DOJ THE NATIVE FILES, AND THEY'RE GOING TO
10:37AM 18 RUN THE SEARCHS ON THEIR SOFTWARE.

10:37AM 19 SO WE ARE WORKING ON LONG-TERM IMPROVEMENTS THROUGH OUR
10:37AM 20 DOCUMENT COLLECTION AND SEARCH CAPABILITIES, AND IT'S A HIGH
10:37AM 21 AGENCY PRIORITY TO GET OUR E-DISCOVERY CAPABILITIES ON A STRONG
10:37AM 22 FOOTING, AND THIS HAS GARNERED SIGNIFICANT AGENCY LEADERSHIP
10:37AM 23 ATTENTION, BUT THERE ARE MANY LONG-TERM FIXES THAT REQUIRE A
10:37AM 24 SIGNIFICANT INVESTMENT OF MONEY AND TALENT AND THEY CAN'T TAKE
10:37AM 25 EFFECT ON THE TIMELINE THAT THE COURT HAS ORDERED. IT'S JUST

10:37AM 1 NOT TECHNICALLY POSSIBLE.

10:37AM 2 SO IN THE MEANTIME WE ARE BRINGING EVERY RESOURCE TO BEAR

10:37AM 3 THAT WOULD BE HELPFUL TO THE PRODUCTION.

10:37AM 4 THE DOJ IS CUTTING DOWN ON A TREMENDOUS AMOUNT OF

10:37AM 5 PRODUCTION TIME BY TAKING POSSESSION OF THE DOCUMENTS AND

10:37AM 6 RUNNING THE SEARCHS, AND WE ARE NOT AWARE OF ANY OTHER

10:37AM 7 RESOURCES THAT DOJ COULD OFFER AT THIS TIME OR THAT THE FDA

10:37AM 8 COULD BRING TO BEAR THAT WOULD ALLOW US TO OVERCOME THE

10:37AM 9 TECHNICAL LIMITATIONS THAT WE HAVE TO WORK WITHIN.

10:37AM 10 SO I APOLOGIZE TO THE COURT THAT I WAS NOT ABLE TO ATTEND

10:38AM 11 THE HEARING IN PERSON, BUT WE DID SEND THREE ATTORNEYS FROM FDA

10:38AM 12 TO BE THERE IN PERSON, INCLUDING OUR VERY EXPERIENCED ATTORNEY

10:38AM 13 WE HIRED FROM ONE OF THE BIG D.C. LAW FIRMS TO OVERSEE OUR

10:38AM 14 E-DISCOVERY WORK, AND THEY COULD ANSWER ANY QUESTIONS THAT THE

10:38AM 15 COURT HAS OR I WOULD BE HAPPY TO.

10:38AM 16 AND I DO APPRECIATE THE OPPORTUNITY TO ADDRESS YOU.

10:38AM 17 THE COURT: WELL, THANK YOU, MS. AMIN. I APPRECIATE

10:38AM 18 YOU JOINING THE CONVERSATION. I KNOW YOU HAVE A BUSY SCHEDULE.

10:38AM 19 THIS IS AN IMPORTANT MATTER, AND I'M GRATEFUL FOR THE ATTENTION

10:38AM 20 THAT YOU'VE PLACED TO THIS.

10:38AM 21 I WAS GOING TO ASK YOU WHETHER OR NOT -- WE HEARD

10:38AM 22 MR. LEACH SAY THAT JUSTICE IS READY AND ABLE TO PROVIDE BODIES

10:38AM 23 AND ABLE ASSISTANCE, BUT WHAT I HEARD YOU SAY IS -- I THINK I

10:38AM 24 HEARD YOU SAY THAT ANYTHING THAT JUSTICE COULD DO AS FAR AS

10:38AM 25 MORE BODIES IS NOT -- WOULD NOT BE HELPFUL.

10:38AM 1 MS. AMIN: AND THEY'RE PROVIDING BODIES ON THE
10:39AM 2 SEARCHES, AND THAT HAS BEEN A HUGE HELP. I CAN -- OUR ORIGINAL
10:39AM 3 ESTIMATES FOR HOW LONG IT WOULD TAKE TO COMPLY WITH THIS WERE A
10:39AM 4 NUMBER OF MONTHS THAT YOU WON'T EVEN WANT TO HEAR US MENTION IN
10:39AM 5 THIS COURT, BUT DOJ HAS PROVIDED THE RESOURCES TO RUN THE
10:39AM 6 SEARCH WHICH HAS BROUGHT US TO THE POINT OF BEING ABLE TO
10:39AM 7 COMMIT TO APRIL, AND THAT HAS BEEN A TREMENDOUS HELP.
10:39AM 8 BUT THERE ARE NOT ANY OTHER RESOURCES THAT THEY COULD
10:39AM 9 OFFER THAT WOULD CHANGE THESE FUNDAMENTAL LIMITATIONS THAT WE
10:39AM 10 HAVE.
10:39AM 11 THE COURT: IF YOU OBTAINED THE INFORMATION AND GAVE
10:39AM 12 IT TO, AS THEY'RE DOING, I GUESS THE NATIVE DOCUMENTS TO
10:39AM 13 JUSTICE NOW, AND THEY'RE DOING THE SEARCH WITH THEIR BODIES,
10:39AM 14 THEIR TEAM, IS THAT SOMETHING THAT CAN BE ENHANCED, THAT IS,
10:39AM 15 THE DELIVERY OF THE NATIVE DOCUMENTS, OR IS THAT TIED INTO THIS
10:39AM 16 OTHER SOFTWARE ISSUE?
10:39AM 17 MS. AMIN: YEAH, IT'S THAT AND WE CONTINUE -- YOU
10:39AM 18 KNOW, EVERY DAY WE'RE LOOKING FOR WAYS THAT WE CAN MAKE THAT
10:39AM 19 DELIVERY OF THE NATIVE DOCUMENTS GO FASTER, BUT AS OF RIGHT NOW
10:40AM 20 WE'RE NOT AWARE OF ANYTHING ELSE THAT WE COULD -- WE'VE TAKEN
10:40AM 21 EVERY STEP THAT WE CAN IDENTIFY THAT WE CAN TAKE WITHIN THE
10:40AM 22 TIME PERIOD THAT WE HAVE.
10:40AM 23 BUT WE CONTINUE TO HAVE LEADERSHIP CONVERSATIONS ABOUT
10:40AM 24 THIS WITH OUR LEADERSHIP AND THE I.T. EXPERTS, AND CERTAINLY IF
10:40AM 25 WE IDENTIFY ADDITIONAL WAYS THAT WE CAN MAKE THIS MOVE FASTER,

10:40AM 1 IF ANY OF IT WOULD INVOLVE ANY RESOURCES FROM DOJ, WE WOULD NOT
10:40AM 2 HESITATE TO ASK.

10:40AM 3 THE COURT: OKAY. THANK YOU. I'M CURIOUS, HOW WAS
10:40AM 4 THE APRIL 30TH DATE ARRIVED AT? HOW WAS THAT REACHED?

10:40AM 5 MS. AMIN: I CAN DEFER TO MY COLLEAGUES WHO ARE
10:40AM 6 THERE IN THE COURTROOM IF THEY'RE ABLE TO WALK THROUGH STEP BY
10:40AM 7 STEP, BUT IT'S JUST A MATTER OF 88 CUSTODIANS AND GAMING OUT
10:40AM 8 HOW MUCH TIME THE SYSTEM IS TAKING TO ELECTRONICALLY DOWNLOAD
10:40AM 9 COMBINED WITH HOW MUCH TIME WOULD IT TAKE TO VISIT TO MANUALLY
10:40AM 10 COLLECT.

10:40AM 11 THE COURT: OKAY. WELL, MAYBE I'LL TURN TO --

10:41AM 12 MR. WEINFIELD, ARE YOU THE BEST TO ANSWER THAT QUESTION, SIR?

10:41AM 13 MR. WEINFIELD: YES.

10:41AM 14 THE COURT: SURE, WHY DON'T YOU COME FORWARD. I'M
10:41AM 15 CURIOUS, IS THERE AN APP? IS THERE AN ALGORITHM OR SOMETHING?
10:41AM 16 HOW IS THAT REACHED?

10:41AM 17 MR. WEINFIELD: THANK YOU, YOUR HONOR. THANK YOU,
10:41AM 18 YOUR HONOR. THAT WAS BASED ON MY PROJECTION OF THE DOCUMENTS
10:41AM 19 THAT WE HAD PRODUCED TO -- HAD TRANSMITTED TO DOJ TO DATE AT
10:41AM 20 THE TIME I CAME UP WITH THE PROJECTION, PLUS THE INFORMATION
10:41AM 21 THAT I WAS GIVEN FROM OUR I.T. STAFF ABOUT HOW LONG IT WOULD
10:41AM 22 TAKE PER CUSTODIAN FOR EACH OF THE E-MAILS AND THE NETWORK
10:41AM 23 DRIVES AND THE ARCHIVED CUSTODIANS.

10:41AM 24 THE COURT: SO HAS YOUR ESTIMATE CHANGED IN LIGHT OF
10:41AM 25 WHAT WE LEARNED FROM MS. AMIN AND MR. LEACH ABOUT THE

10:41AM 1 PRODUCTION?

10:41AM 2 IT SOUNDS LIKE IT HAS BEEN ALL HANDS ON DECK AND THERE HAS

10:41AM 3 BEEN SOME EFFICIENCIES THAT HAVE BEEN CAPTURED. HAS THAT

10:41AM 4 CHANGED YOUR ESTIMATE?

10:41AM 5 MR. WEINFIELD: I HAVEN'T CREATED A FORMAL ESTIMATE,

10:41AM 6 YOUR HONOR, BUT I AM -- I WOULD BE DELIGHTED IF WE WERE ABLE TO

10:41AM 7 PRODUCE ALL OF THE DOCUMENTS PRIOR TO APRIL 30TH.

10:42AM 8 I WOULDN'T GO SO FAR AS TO SAY THAT I'M HOPEFUL OF THAT,

10:42AM 9 BUT I THINK THERE IS A POSSIBILITY OF THAT. I CERTAINLY WOULD

10:42AM 10 NOT WANT TO COMMIT TO THAT AT THIS TIME.

10:42AM 11 IF IT PLEASE THE COURT, WE ARE ENGAGED IN QUITE A COMPLEX

10:42AM 12 PROCESS. WE'VE DESCRIBED IT AS BUILDING A BOAT WHILE YOU'RE IN

10:42AM 13 THE WATER.

10:42AM 14 SO EVERY DAY WE'RE TRYING TO FIND NEW EFFICIENCIES AND SO

10:42AM 15 IT WOULD BE IMPRUDENT TO COME UP WITH A SPECIFIC ESTIMATE NOW.

10:42AM 16 NOW, IF THE COURT WISHES ONE, I'D BE HAPPY TO GET BACK IN

10:42AM 17 TOUCH WITH MY COLLEAGUES AND COME UP WITH ONE.

10:42AM 18 THE COURT: I WAS CURIOUS, THIS DATE WAS SELECTED

10:42AM 19 AND I'VE HEARD THE REASONS PERHAPS NOW.

10:42AM 20 MR. WEINFIELD: DRILLING DOWN JUST A LITTLE BIT, IT

10:42AM 21 HAD TO DO WITH HOW MANY CUSTODIANS WE COULD COLLECT

10:42AM 22 CONCURRENTLY, HOW LONG IT MIGHT TAKE TO PROCESS THAT DATA, HOW

10:42AM 23 LONG IT WOULD TAKE TO, AS MS. AMIN COMMENTED EARLIER, REHYDRATE

10:42AM 24 THE CUSTODIANS. THAT'S A PARTICULARLY DIFFICULT PROCESS THAT

10:42AM 25 REQUIRES SOMEONE WITH EXPERTISE AND EXPERIENCE IN THAT AREA.

10:42AM 1 SO I PUT THOSE NUMBERS TOGETHER AND CAME UP WITH THAT

10:43AM 2 BASED ON A VERY GRANULAR ANALYSIS.

10:43AM 3 THE PLACES WHERE WE MIGHT GAIN SPEED MIGHT BE IN THE

10:43AM 4 E-MAIL COLLECTION, PERHAPS A BIT OF SPEED ON THE NETWORK

10:43AM 5 COLLECTION.

10:43AM 6 BUT BEING PRUDENT, APRIL 30TH IS A DEADLINE THAT WE CAN

10:43AM 7 CERTAINLY MEET.

10:43AM 8 THE COURT: GREAT. THANK YOU VERY MUCH. THANK YOU

10:43AM 9 FOR BEING HERE.

10:43AM 10 MR. WEINFIELD: YOU'RE VERY WELCOME.

10:43AM 11 MR. LEACH, ANYTHING ELSE YOU WOULD LIKE TO ADD?

10:43AM 12 MR. LEACH: NO, YOUR HONOR. THANK YOU VERY MUCH.

10:43AM 13 THE COURT: ALL RIGHT. THANK YOU. WHO IS GOING TO

10:43AM 14 SPEAK FOR THE DEFENSE?

10:43AM 15 MR. WADE: LANCE WADE ON BEHALF OF THE DEFENSE.

10:43AM 16 HAPPY NEW YEAR. IT'S NICE TO BE BACK IN CALIFORNIA.

10:43AM 17 THE COURT: THANKS. HAPPY NEW YEAR.

10:43AM 18 MR. WADE: THE -- WE DON'T WANT TO -- WE HEAR

10:43AM 19 EVERYTHING THAT'S BEEN SAID HERE, AND WE DON'T WANT TO APPEAR

10:43AM 20 UNREASONABLE OR UNAPPRECIATIVE.

10:43AM 21 THE COURT: BUT.

10:43AM 22 MR. WADE: THERE'S A TREMENDOUS AMOUNT OF WORK. THE

10:43AM 23 BUT WILL COME IN A SECOND. THERE'S A TREMENDOUS AMOUNT OF WORK

10:44AM 24 BEING DONE, AND I DON'T WANT TO BE DISRESPECTFUL OF THAT GIVEN

10:44AM 25 THE HARD WORK THAT IS BEING PUT IN BY PEOPLE -- THE OPPOSING

10:44AM 1 COUNSEL AND PEOPLE WITH THE GOVERNMENT.

10:44AM 2 THE COURT: IT SEEMS LIKE IT'S A SIGNIFICANT EFFORT

10:44AM 3 THAT HAS BEEN CALLED UPON, AND WHAT WE'VE HEARD TODAY AND IN

10:44AM 4 THE DECLARATIONS SUGGESTS THAT THEY'VE RISEN TO THE CHALLENGE

10:44AM 5 AS BEST THEY CAN WITH THE TOOLS THAT THEY HAVE AVAILABLE.

10:44AM 6 MR. WADE: IT WOULD SEEM LIKE THERE IS SOME

10:44AM 7 BOTTLENECKS IN THE PROCESS BASED ON THE TECHNOLOGY THAT THEY

10:44AM 8 EMPLOY AT THE AGENCY THAT ARE LIMITING THE CAPACITY HERE AND

10:44AM 9 WITHOUT -- I DON'T HAVE THE TECHNICAL CAPACITY TO TELL THE

10:44AM 10 COURT THAT THERE IS SOME ALTERNATIVE TO FIX THAT BOTTLENECK.

10:44AM 11 IT'S POSSIBLE THAT SOME OUTSIDE VENDOR CAN BE BROUGHT IN, BUT

10:44AM 12 IT SOUNDS LIKE THEY'RE MAKING GREAT EFFORTS TO TRY TO DO THAT

10:44AM 13 AND TO DEVELOP WHATEVER RESOURCES THEY CAN BRING TO THIS

10:44AM 14 MATTER. WE'RE APPRECIATIVE OF THAT.

10:44AM 15 OUR POSITION ON THIS MOTION IS NOT GUIDED BY OUR LACK OF

10:45AM 16 APPRECIATION OF THOSE EFFORTS.

10:45AM 17 IT'S JUST GUIDED BY A PRACTICAL REALITY OF THE CALENDAR,

10:45AM 18 WHICH IS THE VOLUME OF DOCUMENTS HERE, AND THERE'S A LOT OF

10:45AM 19 DISCUSSION THAT HAS BEEN -- THAT HAS OCCURRED WITH RESPECT TO

10:45AM 20 THE SEARCH TERMS AND THE NUMBER OF CUSTODIANS.

10:45AM 21 THE PROOF IS IN THE PUDDING HERE, YOUR HONOR. ONE HUNDRED

10:45AM 22 AND FORTY THOUSAND DOCUMENTS HAVE COME TO THE DEFENSE THAT ARE

10:45AM 23 RESPONSIVE TO THOSE SIX CATEGORIES OF DOCUMENTS.

10:45AM 24 I REVIEWED A STACK OF THEM ON THE PLANE RIDE OUT HERE, THE

10:45AM 25 MORE RECENT MATERIALS. THESE ARE DOCUMENTS THAT ARE MATERIAL

10:45AM 1 TO THE PREPARATION OF THE DEFENSE AND SIGNIFICANT DOCUMENTS.

10:45AM 2 SO WE NEED THE MATERIAL. WE NEED TIME TO DIGEST THE

10:45AM 3 MATERIAL, AND WE CAN'T DO THAT AND BE READY TO MEET THE VARIOUS

10:45AM 4 DEADLINES THAT HAVE BEEN IMPOSED BY THE COURT OR THAT WE HAVE

10:45AM 5 PREVIOUSLY AGREED TO WITH THE ASSUMPTION THAT WE WOULD HAVE

10:45AM 6 THIS MATERIAL EARLIER.

10:45AM 7 THE COURT: WELL, DID YOU RECEIVE 136,092 DOCUMENTS

10:46AM 8 BY DECEMBER 31ST?

10:46AM 9 MR. WADE: WE DID. I USED THE NUMBER OF ABOUT

10:46AM 10 140,000 BECAUSE I THINK THERE IS ANOTHER SMALL PRODUCTION THAT

10:46AM 11 WAS MADE BEFORE THEN. THE PRECISE NUMBER MIGHT BE --

10:46AM 12 THE COURT: RIGHT. RIGHT. HAVE YOU COMPLETED YOUR

10:46AM 13 WORK?

10:46AM 14 MR. WADE: NO.

10:46AM 15 THE COURT: RIGHT.

10:46AM 16 MR. WADE: AND TO THAT POINT, YOUR HONOR, WHICH IS

10:46AM 17 EXACTLY WHY WE TAKE THE POSITION THAT WE'RE TAKING BEFORE THE

10:46AM 18 COURT, I DID SOME MATH ON THIS LAST NIGHT AS I WAS GOING

10:46AM 19 THROUGH IT, AND USING, USING THE AVERAGE RETURN, AVERAGE REVIEW

10:46AM 20 RATES FOR DOCUMENTS OF THIS TYPE AND BASED ON THE REVIEW RATE

10:46AM 21 OF THE PREVIOUS DOCUMENTS THAT WE'VE RECEIVED, IT WOULD TAKE A

10:46AM 22 REVIEW TEAM TEN -- OF TEN PEOPLE, ABOUT THREE MONTHS JUST TO

10:46AM 23 GET THROUGH JUST THE FIRST TRANCHE OF DOCUMENTS WITH A

10:46AM 24 COMPREHENSIVE FIRST LEVEL REVIEW.

10:46AM 25 THAT'S TO SAY NOTHING OF THE FOLLOW-ON ANALYSIS THAT IS

10:46AM 1 DONE BY ASSOCIATES AND PARTNERS TO INTEGRATE THAT INTO OUR
10:46AM 2 EXPERT WORK, TO INTEGRATE THAT INTO THE WORK THAT WE'RE DOING
10:47AM 3 TO BE PREPARED TO EXAMINE WITNESSES, THE INVESTIGATIVE WORK
10:47AM 4 THAT WE WANT TO DO TO DETERMINE WHETHER WE CALL ADDITIONAL
10:47AM 5 WITNESSES.

10:47AM 6 SO WE'RE, WE'RE -- LIKE THE GOVERNMENT AND THE FDA, WE'RE
10:47AM 7 PREPARED TO WORK VERY HARD ON THIS, BUT THERE'S JUST A
10:47AM 8 PRACTICAL REALITY BASED UPON THE VOLUME HERE TO BE IN A
10:47AM 9 POSITION WHERE WE CAN PROPERLY DEFEND OUR CLIENT, WE CAN'T
10:47AM 10 AGREE TO THIS DEADLINE.

10:47AM 11 OF COURSE, WE WISH THESE RESOURCES HAD BEEN DEDICATED
10:47AM 12 SOONER. WE WISHED THAT THIS HAPPENED BACK IN -- WHEN WE FILED
10:47AM 13 THE MOTION IN APRIL OR AT THE PRIOR HEARINGS.

10:47AM 14 THE COURT: WELL, MS. AMIN TELLS US THIS IS A CASE
10:47AM 15 OF FIRST IMPRESSION TO HER AGENCY, THE SIZE OF THE REQUEST.

10:47AM 16 MR. WADE: I CERTAINLY CAN'T SPEAK TO THE FDA'S
10:47AM 17 EXPERIENCE ON THESE MATTERS. I CAN REPRESENT TO THE COURT, AS
10:47AM 18 WE HAVE MENTIONED BEFORE, WE HAVE DONE A LOT OF CRIMINAL
10:47AM 19 LITIGATION INVOLVING VARIOUS GOVERNMENT AGENCIES, GIVEN OUR
10:48AM 20 PRACTICE AND THE LOCATION OF OUR PRACTICE, AND RECEIVING A
10:48AM 21 VOLUME OF THIS SIZE FROM A GOVERNMENT AGENCY IN CONNECTION WITH
10:48AM 22 A CRIMINAL CASE IS NOT UNPRECEDENTED IN OUR EXPERIENCE.

10:48AM 23 NOW --

10:48AM 24 THE COURT: WITH THE FDA IN YOUR EXPERIENCE?

10:48AM 25 MR. WADE: NOT WITH -- I HAVE NOT HAD THAT WITH THE

10:48AM 1 FDA BUT OTHER AGENCIES WE HAVE SEEN SIMILAR VOLUME.

10:48AM 2 NOW, TO BE CLEAR, A LOT OF TIMES THOSE MATERIALS ARE

10:48AM 3 GATHERED AS PART OF THE INVESTIGATION, AND A BROADER SET OF

10:48AM 4 RELEVANT MATERIALS IS GATHERED DURING THE INVESTIGATION STAGE

10:48AM 5 AND TURNED OVER.

10:48AM 6 IT WAS CLEAR TO US AT THE OUTSET THAT THE UNIVERSE OF

10:48AM 7 MATERIAL THAT WAS GATHERED HERE WAS VERY NARROW AND TO A DEGREE

10:48AM 8 CURATED TO THE GOVERNMENT'S CASE, THE CASE THAT IT WANTED TO

10:48AM 9 PRESENT, WHICH IS FINE. THE GOVERNMENT HAS ITS JOB. WE HAVE

10:48AM 10 OURS.

10:48AM 11 OUR JOB IS TO DEFEND OUR CLIENT, AND, THEREFORE,

10:48AM 12 ADDITIONAL MATERIALS ARE RELEVANT TO THOSE EFFORTS.

10:48AM 13 I MIGHT BE IN A DIFFERENT POSITION IF THESE ROLLING

10:49AM 14 PRODUCTION THAT HAD OCCURRED TO DATE WERE NOT YIELDING RESULTS

10:49AM 15 THAT WE WOULD REPRESENT TO THE COURT TO BE HIGHLY SIGNIFICANT

10:49AM 16 DOCUMENTS, EXHIBIT LIST TYPE DOCUMENTS. AND WE HAVE EVERY

10:49AM 17 REASON TO ANTICIPATE THAT THAT WILL CONTINUE.

10:49AM 18 NOW, THAT BEING SAID, WE'VE, WE'VE -- WE'RE LEARNING NEW

10:49AM 19 INFORMATION, SOME OF THE INFORMATION THAT HAS BEEN SHARED BY

10:49AM 20 FDA COUNSEL AND HAS BEEN SHARED BY THE GOVERNMENT TODAY WE'RE

10:49AM 21 ACTUALLY LEARNING FOR THE FIRST TIME IN THE COURTROOM WITH

10:49AM 22 RESPECT TO SOME OF THE ISSUES, AND THE TYPE OF PROPOSAL THAT

10:49AM 23 THEY'RE MAKING WITH RESPECT TO SOME OF THOSE CUSTODIANS WHO ARE

10:49AM 24 LOWER PRIORITY CUSTODIANS, MANY OF WHOM ARE LAWYERS, AND I'M

10:49AM 25 CONFIDENT THAT IN AN EFFORT TO TRY TO EXPEDITE THIS WE PROBABLY

10:49AM 1 COULD COME UP WITH A PROCESS THAT WOULD ALLOW FOR A MANUAL
10:49AM 2 SEARCH WITH THE TYPES OF PROCEDURES THAT MS. AMIN WAS REFERRING
10:49AM 3 TO WITH SOME FDA ATTORNEY SUPERVISION, DOJ ATTORNEY
10:50AM 4 SUPERVISION, MAYBE A CERTIFICATION FROM THE PERSON THAT THEY
10:50AM 5 DID WHAT THEY SAID THEY COULD DO. I THINK WE CAN COME UP WITH
10:50AM 6 A PROTOCOL TO HELP EXPEDITE IT.
10:50AM 7 BUT MY UNDERSTANDING OF WHAT THE GOVERNMENT'S POSITION IS,
10:50AM 8 EVEN WITH THAT EFFICIENCY, WE'RE STILL LOOKING AT THE END OF
10:50AM 9 APRIL, WHICH IS A DEADLINE THAT I THINK, AS THE COURT KNOWS,
10:50AM 10 INCLUDES -- THE VERY DATE IS THE DATE ON WHICH OUR EXPERT
10:50AM 11 DISCLOSURES ARE DUE, IT'S JUST A DAY BEFORE OUR RULE 16
10:50AM 12 DISCOVERY IS DUE. IT'S JUST --
10:50AM 13 THE COURT: WELL, WE CAN MAKE SOME ADJUSTMENT, OF
10:50AM 14 COURSE, AS NEEDED ON THINGS. COURTS DO THAT.
10:50AM 15 BUT I APPRECIATE YOUR ATTENTION TO RESPECTING THE
10:50AM 16 DEADLINES.
10:50AM 17 MR. WADE: AND WE HAVE MADE EVERY EFFORT TO TRY TO
10:50AM 18 PUSH TOWARDS THAT.
10:50AM 19 YOUR HONOR MAY RECALL THAT AS FAR BACK AS JUNE AND JULY
10:50AM 20 WHEN WE WERE IN OUR FIRST AND SECOND HEARING ON THESE MATTERS
10:51AM 21 AND WERE AT THE SAME TIME TALKING ABOUT THE TRIAL, WE
10:51AM 22 ARTICULATED, BECAUSE THE COURT ADVANCED THE TRIAL DATE SLIGHTLY
10:51AM 23 OVER WHAT THE PARTIES HAD OFFERED TO THE COURT, WE TRIED TO
10:51AM 24 MAKE CLEAR TO THE COURT THAT WE SAW LITTLE ROOM FOR ERROR IN
10:51AM 25 CONNECTION WITH SOME OF THESE DISCOVERY ISSUES GIVEN HOW TIGHT

10:51AM 1 THIS IS.

10:51AM 2 THIS IS A -- THIS CASE AND IN THE PROCESS THE FDA IS GOING

10:51AM 3 THROUGH IS IN SOME WAYS A MICROCOSM OF THE WHOLE CASE. IT'S A

10:51AM 4 HIGHLY COMPLEX CASE, AND IT'S GOING TO BE A LENGTHY TRIAL AND

10:51AM 5 IT INVOLVES A LOT OF WITNESSES. THERE IS ONLY SO MUCH WE CAN

10:51AM 6 DO AND BE IN A POSITION TO FULLY AND FAIRLY REPRESENT OUR

10:51AM 7 CLIENT BEFORE THE COURT AT TRIAL AND EFFICIENTLY BEFORE THE

10:51AM 8 COURT. WE DON'T WANT TO -- WE WANT TO DO IT IN A WAY THAT IS

10:51AM 9 RESPECTFUL OF THE COURT OBVIOUSLY IN ITS TIME AS WELL.

10:51AM 10 SO THAT IS THE GENESIS OF OUR OPPOSITION.

10:51AM 11 THE COURT: WELL, I APPRECIATE IT. I'VE OFTEN

10:52AM 12 COMMENTED IT'S -- I'VE DONE THIS, I'VE USED THE WORD

10:52AM 13 "EFFICIENT" WITH A CRIMINAL CASE, AND IT'S PROBABLY NOT

10:52AM 14 APPROPRIATE TO DO THAT, RESPECTING ALL PARTIES' INTERESTS IN

10:52AM 15 THE CASE. EFFICIENCY IS IMPORTANT, BUT RESPECTING BOTH

10:52AM 16 PARTIES' RIGHTS TO A FAIR TRIAL IS PARAMOUNT, SO I APPRECIATE

10:52AM 17 THAT.

10:52AM 18 MR. WADE: YOUR HONOR, TO BE CLEAR, I THINK THAT ALL

10:52AM 19 PARTIES HERE, ESPECIALLY AFTER THE NOVEMBER ORDER, PARTICULARLY

10:52AM 20 AFTER THE NOVEMBER ORDER, HAVE BEEN WORKING DILIGENTLY TO TRY

10:52AM 21 TO BE, IF NOT EFFICIENT, EXPEDITIOUS TO HELP GET -- KEEP THIS

10:52AM 22 CASE ON TRACK, AND I'M NOT BELITTLING THOSE EFFORTS, I'M JUST

10:52AM 23 REFLECTING THE REALITY.

10:52AM 24 WE NEED TO BE -- AS YOUR HONOR KNOWS, WE NEED TO BE

10:52AM 25 THOROUGH AND ZEALOUS, I BELIEVE, IN OUR REPRESENTATION OF OUR

10:52AM 1 CLIENT, AND TO DO THAT WE WOULD NOT BE ABLE TO DO THAT ON THE
10:52AM 2 SCHEDULE.

10:52AM 3 THE COURT: OKAY. ALL RIGHT. THANK YOU.

10:52AM 4 MR. BROWN, MR. CAZARES.

10:53AM 5 MR. CAZARES: THANK YOU. THANK YOU.

10:53AM 6 STEPHEN CAZARES FOR MR. BALWANI. I WON'T REITERATE WHAT
10:53AM 7 COUNSEL HAS ALREADY MENTIONED WITH RESPECT TO THE NEED FOR
10:53AM 8 THESE IMPORTANT MATERIALS. I THINK THAT HAS ALREADY BEEN MADE
10:53AM 9 CLEAR.

10:53AM 10 BUT THE CIRCUMSTANCE THAT WE'RE NOW IN FROM THE DEFENSE
10:53AM 11 PERSPECTIVE, OUT OF KIND OF NO FAULT OF OUR OWN, YOU KNOW, THE
10:53AM 12 GOVERNMENT CHOSE TO BRING THIS CASE 19 MONTHS AGO NOW.

10:53AM 13 THE COURT: WELL, I WOULD -- I'M MORE INTERESTED IN
10:53AM 14 NOT CASTING BLAME BUT FINDING SOLUTIONS.

10:53AM 15 MR. CAZARES: AND I'M NOT CASTING BLAME. MY POINT,
10:53AM 16 THOUGH, IS THAT WE'RE NOW AT THIS STAGE WITH TRIAL APPROACHING
10:53AM 17 AND VOLUMINOUS MATERIALS ARE NOW BEING PRODUCED TO THE DEFENSE,
10:53AM 18 WHICH WE REALLY APPRECIATE. AND AS COUNSEL MENTIONED, YOU
10:53AM 19 KNOW, WE'RE PUT IN THIS TIME PRESSURE WHERE WE NEED TO REVIEW
10:53AM 20 THESE MATERIALS TO PREPARE FOR TRIAL, BUT THERE'S THE
10:53AM 21 COUNTERVAILING INTEREST, WE WANT TO GET THIS CASE DONE. WE
10:53AM 22 WOULD LIKE TO GO TO TRIAL. MR. BALWANI WOULD LIKE TO CLEAR HIS
10:53AM 23 NAME. THAT'S THE SPEEDY TRIAL ACT ISSUE.

10:54AM 24 THE PROBLEM NOW IS THAT WE'RE BEING PUT IN THE SITUATION
10:54AM 25 THROUGH -- OUT OF NO INTENT I DON'T BELIEVE BY THE GOVERNMENT,

10:54AM 1 WE'RE BEING PUT IN THE POSITION OF KIND OF WEIGHING OUR NEED TO
10:54AM 2 PREPARE FOR TRIAL VERSUS OUR DESIRE TO GET TO TRIAL AND TO TRY
10:54AM 3 TO CLEAR MR. BALWANI'S NAME, AND THAT'S WHAT IS HAPPENING HERE
10:54AM 4 IN THE COURT, AND THEN THERE ARE OTHER COUNTERVAILING ISSUES
10:54AM 5 THAT WE ON THE DEFENSE HAVE TO CONSIDER AS WELL. THAT'S,
10:54AM 6 UNFORTUNATELY, YOU KNOW, THE MEDIA COVERAGE OF THE CASE, PUBLIC
10:54AM 7 PERCEPTIONS. THERE'S APPARENTLY A MOVIE THAT IS GOING TO BE
10:54AM 8 COMING OUT SOME TIME ABOUT THESE EVENTS, WHICH I'M SURE AREN'T
10:54AM 9 GOING TO CAST MY CLIENT IN A POSITIVE LIGHT AND MAY HAVE SOME
10:54AM 10 IMPACT ON THE JURY POOL AS WELL.
10:54AM 11 AND THESE ARE -- I KNOW THE COURT CAN'T CONTROL THAT, BUT
10:54AM 12 THESE ARE ALL THINGS THAT WE HAVE TO CONSIDER WHEN TRYING TO
10:54AM 13 MAKE OUR DECISIONS GOING FORWARD WITH RESPECT TO, YOU KNOW,
10:54AM 14 REVIEWING THIS DISCOVERY AND ULTIMATELY THE DIFFICULT CALENDAR
10:54AM 15 WE'RE IN RIGHT NOW.
10:55AM 16 THE COURT: OKAY. THANK YOU.
10:55AM 17 MR. CAZARES: THANK YOU, YOUR HONOR.
10:55AM 18 THE COURT: THANK YOU FOR THOSE OBSERVATIONS.
10:55AM 19 MR. LEACH, ANYTHING FURTHER?
10:55AM 20 MR. LEACH: VERY BRIEFLY, YOUR HONOR. THIS IS -- I
10:55AM 21 DON'T WANT TO LOSE SIGHT OF THE FACT THAT, FIRST OF ALL,
10:55AM 22 MR. BALWANI IS NOT HERE BECAUSE HE'S DEPOSING TEN FDA WITNESSES
10:55AM 23 BACK IN WASHINGTON, D.C. I THINK MR. BALWANI HAS A VERY GOOD
10:55AM 24 UNDERSTANDING OF THE FDA ISSUES AND WAS PREPARED ENOUGH TO GO
10:55AM 25 FORWARD WITH THOSE DEPOSITIONS IN THE CIVIL CASE, SO I DON'T

10:55AM 1 WANT TO LOSE SIGHT OF THE FACT THAT THIS IS ONE ISSUE IN THE
10:55AM 2 INDICTMENT.

10:55AM 3 THERE ARE AT LEAST TEN OTHER CATEGORIES OF
10:55AM 4 MISREPRESENTATIONS HERE. THIS IS NOT A CASE ABOUT THE FDA
10:55AM 5 INVOLVING THE FDA CHARGES. I DON'T WANT TO MINIMIZE THE
10:55AM 6 IMPORTANCE OF THESE DOCUMENTS, AND WE ARE RESPONDING TO THE SIX
10:55AM 7 CATEGORIES IN THE MOTION TO COMPEL. I'M NOT TRYING TO MINIMIZE
10:56AM 8 THEM. I'M JUST TRYING TO PUT THEM IN PERSPECTIVE OF A MUCH
10:56AM 9 LARGER CASE. THIS IS NOT A CASE ABOUT THE FDA. THIS IS A CASE
10:56AM 10 ABOUT MISREPRESENTATIONS TO INVESTORS AND REPRESENTATIONS --

10:56AM 11 THE COURT: IT'S A WIRE FRAUD CASE.

10:56AM 12 MR. LEACH: IT'S A WIRE FRAUD CASE AS I UNDERSTAND
10:56AM 13 IT, TOO, YOUR HONOR.

10:56AM 14 SO I ALSO -- I TAKE THE DEFENSE AT THEIR WORD THAT THEY
10:56AM 15 NEED THE TIME TO PREPARE. THEY'RE BEST ABLE TO SPEAK TO
10:56AM 16 THOSE -- BETTER ABLE TO SPEAK TO THOSE THAN I AM.

10:56AM 17 I WOULD ENCOURAGE THE MORE SPECIFICS THAT WE CAN HAVE ON
10:56AM 18 THAT. YOU KNOW, I KEEP HEARING REFERENCES TO HIGHLY RELEVANT
10:56AM 19 EVIDENCE THAT THEY FOUND IN THE 130-PLUS THOUSAND DOCUMENTS,
10:56AM 20 AND I'M NOT SURE WHAT THEY'RE REFERRING TO. I WOULD ENCOURAGE
10:56AM 21 THE COURT TO LOOK AT THE SPECIFICITY OF THAT.

10:56AM 22 AND WE WANT TO KEEP THIS TRIAL DATE. WE'RE WORKING TO
10:56AM 23 KEEP THIS TRIAL DATE.

10:56AM 24 THE DEFENSE, YOU KNOW, WE TAKE THEM AT THEIR WORD FOR WHAT
10:56AM 25 THEY NEED, AND WE'RE WORKING AS QUICKLY AS WE CAN TO GET IT TO

10:57AM 1 THEM.

10:57AM 2 THANK YOU, YOUR HONOR.

10:57AM 3 THE COURT: ALL RIGHT. I THINK OUR NEXT COURT DATE

10:57AM 4 IS FEBRUARY 10TH.

10:57AM 5 MR. LEACH: YES, YOUR HONOR.

10:57AM 6 THE COURT: THAT IS FOR MOTIONS.

10:57AM 7 LET ME INVITE COUNSEL TO SIDE-BAR, AND IF YOU COULD BRING

10:57AM 8 YOUR CALENDARS, PLEASE. I JUST WANT TO GO OVER SOME SCHEDULING

10:57AM 9 QUESTIONS.

10:57AM 10 **(SIDE-BAR CONFERENCE ON A SEALED RECORD PAGES 41-44)**

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10:57AM 1 (IN OPEN COURT.)

11:01AM 2 THE COURT: ALL RIGHT. THANK YOU, COUNSEL. THEN

11:01AM 3 THE COURT IS NOT GOING TO DISTURB THE FEBRUARY 10TH DATE. I

11:01AM 4 THINK THAT'S BEEN SET, AND THAT WILL REMAIN AS SET FOR FURTHER

11:01AM 5 HEARING.

11:01AM 6 I'M NOT GOING TO DECIDE THE GOVERNMENT'S MOTION NOW. I'M

11:01AM 7 GOING TO TAKE THAT MATTER UNDER SUBMISSION. I MAY HAVE MORE

11:01AM 8 QUESTIONS, AND I MAY ASK THE PARTIES FOR ADDITIONAL INFORMATION

11:01AM 9 ABOUT THIS.

11:01AM 10 MS. AMIN, MR. GORGI, I APPRECIATE YOUR APPEARANCE

11:01AM 11 TELEPHONICALLY.

11:02AM 12 IS THERE ANYTHING ELSE YOU WOULD LIKE TO ADD BEFORE WE END

11:02AM 13 THIS MORNING'S SESSION?

11:02AM 14 MS. AMIN: NOTHING FROM ME. THANK YOU, YOUR HONOR.

11:02AM 15 THE COURT: ALL RIGHT. MR. GORGI, ANYTHING?

11:02AM 16 MR. GORGI: NO, YOUR HONOR. THANK YOU.

11:02AM 17 THE COURT: ALL RIGHT. THANK YOU. LET ME TURN TO

11:02AM 18 THE FDA LAWYERS WHO ARE HERE. ANYTHING ELSE YOU WOULD LIKE ME

11:02AM 19 TO KNOW OR ANYTHING YOU WOULD LIKE TO ADD?

11:02AM 20 MR. WEINFIELD: NOTHING FURTHER, YOUR HONOR.

11:02AM 21 THE COURT: ALL RIGHT. THANK YOU VERY MUCH. THANK

11:02AM 22 YOU FOR BEING HERE. I APPRECIATE YOU COMING OUT. IT'S NICE TO

11:02AM 23 PUT A FACE WITH A VOICE, SO THANK YOU. IT'S NICE TO SEE YOU.

11:02AM 24 ALL RIGHT. FEBRUARY 10TH, FEBRUARY 10TH.

11:02AM 25 THE CLERK: 10:00 A.M.

11:02AM 1 THE COURT: ALL RIGHT. 10:00 A.M. THANK YOU.
11:02AM 2 MR. LEACH: THANK YOU, YOUR HONOR.
11:02AM 3 MR. DOWNEY: THANK YOU, YOUR HONOR.
11:02AM 4 THE CLERK: COURT IS IN RECESS.
11:05AM 5 (COURT ADJOURNED 11:05 A.M.)
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3 CERTIFICATE OF REPORTER
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7 I, THE UNDERSIGNED OFFICIAL COURT REPORTER OF THE UNITED
8 STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA,
9 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO HEREBY
10 CERTIFY:

11 THAT THE FOREGOING TRANSCRIPT, CERTIFICATE INCLUSIVE, IS
12 A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE
13 ABOVE-ENTITLED MATTER.

14 
15

16

IRENE RODRIGUEZ, CSR, RMR, CRR
17 CERTIFICATE NUMBER 8074
18

19 DATED: JANUARY 21, 2020
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